UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

UNITED STATES OF AMERICA *ex rel.* JOSEPH IBANEZ AND JENNIFER DERRICK,	:	Civil Action No. 1:11-CV-029
	:	Judge William O. Bertelsman
BRINGING THIS ACTION ON BEHALF OF THE UNITED STATES OF AMERICA, THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, ILLINOIS, HAWAII, INDIANA, IOWA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, WASHINGTON, WISCONSIN, THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA, AND THE DISTRICT OF COLUMBIA,	:	
Plaintiffs and Relators,	:	
v.	:	
BRISTOL-MYERS SQUIBB COMPANY	:	
and	:	
OTSUKA AMERICA PHARMACEUTICAL, INC.	:	
Defendants.	:	

SECOND AMENDED COMPLAINT

I. INTRODUCTION.

1. *Qui tam* Relators Joseph Ibanez and Jennifer Edwards (formerly known as Jennifer Derrick) bring this action on their own behalf and on behalf of the United States of America, the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Hawaii, Indiana, Iowa, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Washington, Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia to recover damages and penalties arising from Defendants Bristol-Myers Squibb's ("BMS") and Otsuka America Pharmaceutical, Inc.'s ("Otsuka") violations of the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq*., and the respective state FCAs. The violations arise out of requests for payment submitted to Medicaid, Medicare, TRICARE, and other federal and state healthcare programs (hereinafter collectively referred to as "government healthcare programs").

2. Abilify is an atypical anti-psychotic drug. Defendants marketed the prescription drug Abilify for off-label use by Medicare, Medicaid and other government healthcare beneficiaries, including children and elderly people, in direct contravention of Corporate Integrity Agreements with the United States in which Defendants promised not to engage in off-label marketing. Specifically, Defendants marketed Abilify to treat children and adolescents at a time when Abilify was not approved for use in children or adolescents. Once Abilify received limited indications for children and adolescents,

Defendants marketed it for the treatment of depression and associated symptoms in children and adolescents, even though Abilify was never approved, and in fact contained a Black Box warning,[1] for treatment of depression in children and adolescents. Similarly, Defendants marketed Abilify for the treatment of elderly patients with dementia, despite the fact that Abilify carried a Black Box warning for treatment of patients with dementia.

3. Defendants planned and executed their illegal marketing strategy with the purpose of inducing physicians to prescribe Abilify for off-label uses. Defendants' sales forces were instructed to use false and misleading messages to induce prescriptions. Defendants' sales forces were incentivized by a volume-based compensation system to call on providers and increase prescribing habits, without regard to appropriateness of the targets or the legality of the message. Defendants provided their sales forces with target call lists replete with physicians who treated the pediatric and geriatric populations and then measured their performance—up to and including whether to keep them employed—based on the success of the calls to those inappropriate targets.

4. Defendants also induced physicians to prescribe Abilify by offering and paying illegal incentives in violation of the Anti-Kickback Statute, including through paid programs, speaking engagements, lunches, dinners, free samples, and other incentives.

5. The off-label uses for which Defendants marketed Abilify are not

---

[1] A "Black Box" is an FDA-required warning on a prescription drug's label which indicates that the drug can cause serious or life-threatening side-effects. The warning gets its name from the heavy black line which surrounds the warning on the label. A black-box warning is the most serious of five levels of warnings which FDA can require on a label.

supported by any compendia such as those specified by 42 U.S.C. §1396r-8(g)(1)(B)(I) (describing Medicaid drug coverage); and not used in the treatment of a rare disease or condition for which it was approved by the United States Food and Drug Administration ("FDA") or, alternatively, supported by reliable evidence as set forth in 32 C.F.R. §199.2 and TRICARE Policy Manual, Chapter 7, Section 2.1 (describing TRICARE drug coverage). The resulting claims are noncovered and nonpayable by Medicare, Medicaid, and other government healthcare programs.

6. The illegal promotional campaigns and kickback schemes are prohibited by Corporate Integrity Agreements between Defendants and the United States, entered into in 2007 and 2008. Instead of refraining from further off-label promotion and illegal incentive schemes, as required by the Corporate Integrity Agreements, Defendants continued vigorously to market Abilify illegally.

7. Defendants' conduct violated material conditions of payment of claims for Abilify and, if known, would have affected the federal and state governments' decision to pay the claims.

8. Defendants intended and knew that their conduct caused submission of claims to government healthcare programs of Abilify prescriptions which were ineligible for reimbursement.

9. Defendants' conduct violated the False Claims Act. Relators seek to recover damages arising from Defendants' FCA violations and for BMS's wrongful termination of Relators' employment in violation of the anti-retaliation provisions of the FCA.

II. JURISDICTION AND VENUE.

10. This action arises under the United States Civil False Claims Act, 31 U.S.C. § 3729 *et seq*., and the False Claims Acts of the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Hawaii, Indiana, Iowa, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Washington, Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia.

11. The Court has subject-matter jurisdiction pursuant to 31 U.S.C. § 3732 (a)-(b) and 28 U.S.C. § 1331, and has personal jurisdiction over the Defendants because the Defendants do business and are located in this district.

12. Venue lies under 28 U.S.C. 1391 (b), (c) and 31 U.S.C. 3732 (a) because Defendants operate and transact business within this district.

13. The allegations of this Complaint have not been publicly disclosed in a criminal, civil, or administrative hearing, nor in any congressional, administrative, or General Accounting Office report, hearing, audit, or investigation, nor in the news media.

14. Relators are original sources of the information upon which this Complaint is based, as that phrase in used in the False Claims Act and other laws at issue herein.

15. Relators provided disclosure of the allegations of this Complaint to the United States and the respective states prior to filing under the federal False Claims Act and state False Claims Acts, respectively.

III. PARTIES.

16. The real parties in interest to the claims of this action are the United States of America, the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Hawaii, Indiana, Iowa, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Washington, Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia (the states are collectively referred to herein as the Plaintiff States).

17. Relator Joseph Ibanez is a resident of Ohio. He worked as a sales representative for BMS from early 2002 through his wrongful termination on or about July 23, 2010. In 2005, Relator Ibanez was assigned to market Abilify in the BMS Residential Care Division. In October 2007, when that division dissolved, he was assigned to the Neuroscience Division, Account-Based Sales ("ABS") of Abilify. In October 2009, when Neuroscience was again re-organized, Relator Ibanez became a Pediatric-Focused Specialist ("PFS") for Abilify.

18. Relator Jennifer Edwards is a resident of Arizona. She worked as a sales representative for BMS from April 1988 through August 1996, and from November 2005 through her wrongful termination on May 12, 2010. In 2005, Relator Edwards was assigned to the sale of Abilify in the Residential Care Division. In October 2007, when that division dissolved, she was assigned to the Neuroscience Division, Office-Based Sales ("OBS") of Abilify. She remained in OBS when Neuroscience was again re-organized in October 2009, until her termination in May 2010.

19. Defendant Bristol-Myers Squibb is a pharmaceutical company with its corporate headquarters in New York City, New York. It is incorporated in Delaware and transacts business nationwide, including in this district.

20. Defendant Otsuka is a pharmaceutical company headquartered in Tokyo, Japan, with U.S. offices in Rockville, Maryland, Princeton, New Jersey, Maple Grove, Minnesota and Redwood City, California. It is incorporated in Delaware and transacts business nationwide, including in this district.

IV. EVIDENTIARY BASIS FOR RULE 9(B), FED. R. CIV. P. ALLEGATIONS.

21. Relators are familiar with the policies and practices alleged herein as a result of their employment relationship with Defendant BMS and their personal observations of the conduct of both BMS and Otsuka in improperly inducing sales of Abilify through illegal marketing of off-label uses and illegal incentives in violation of the Anti-Kickback Statute.

22. With respect to each allegation herein made upon information and belief, Relators have, based upon their knowledge, data, and experience, a reasoned factual basis to make the allegation but lack complete details of it.

23. However, while Relators have significant evidence of the fraud alleged herein (the details of which follow), much of the documentary evidence necessary to prove the allegations in this Complaint is in the exclusive possession of either the Defendants or the United States.

24. Specifically, Relators do not have access to all of the information regarding the claims for payment caused to be submitted by Defendants. This information is in the exclusive possession and control of the Defendants, the United States, the Plaintiff States, the physicians who prescribed Abilify off-label, and the pharmacies that filled the prescriptions for Abilify.

25. Defendants caused to be submitted and, on information and belief, continue to cause submission of, false claims to government healthcare programs for payment of Abilify for noncovered and nonpayable uses.

26. Defendants' scheme has been in place since at least 2005 and is ongoing.

V. THE STATUTORY AND REGULATORY ENVIRONMENT.

A. Overview: Drug Coverage under Government Healthcare Programs.

27. Congress has the authority to decide which drugs and uses will be paid for by government healthcare programs. As alleged below, Congress has exercised this authority in very specific and considered ways regarding each government program. For "covered outpatient drugs," as that term is defined by statute, Congress has integrated FDA drug restrictions into government healthcare program restrictions regarding what drugs will be covered and paid.

28. Congress has not delegated direct authority to FDA to decide which drugs and uses will be paid by government healthcare programs. Instead, FDA's primary function with respect to drugs and their uses is to receive, evaluate and approve or disapprove specific labels under the 1966 Fair Packaging and Labeling Act, 15 U.S.C. § 1451. Another FDA function is to monitor and enforce companies' compliance

with advertising and promotional restrictions under the Food, Drug, and Cosmetics Act ("FDCA") and the Food and Drug Administration Modernization Act of 1997 ("FDAMA").

29. Under the FDCA, pharmaceutical drug companies cannot distribute a drug in interstate commerce unless FDA has approved its use. 21 U.S.C. §§ 355(a) & (d). After extensive testing, FDA may approve a drug for one or more specific uses and will establish a recommended dosage for those uses. Use of an approved drug for any purposes other than those specifically approved by FDA is referred to as an "off-label" use. The FDCA does not prohibit physicians from prescribing an FDA-approved drug for unapproved off-label uses. The FDCA does, however, specifically prohibit drug companies from marketing or promoting a drug for off-label uses. 21 U.S.C. §§ 331 & 352.

30. Government healthcare programs establish conditions under which they will pay for prescription drugs dispensed to beneficiaries. As alleged more specifically below, these conditions incorporate the FDCA restrictions to define the drugs which will be covered and reimbursed by public healthcare programs. As a general rule, government healthcare programs do not reimburse the cost of drugs prescribed for off-label uses.

31. The knowing and undisclosed failure to comply with FDCA regulations regarding the marketing of approved uses of drugs will cause federal and state governments to pay out benefits for noncovered and nonpayable drugs. They would not make such payments if fully informed.

32. The details of each of the relevant statutory and regulatory systems are included below.

B. The FDA Regulatory System.

33. Under the FDCA, 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Approval of the drug by FDA is the final step in a multi-year process of study and testing, and pharmaceutical concerns initiate the approval process by filing a New Drug Application ("NDA").

34. FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved for treatment of specific conditions, for which the drug has been extensively tested in animal subjects and human patients. Each specific approved use is called an "indication" for which the drug may be prescribed. FDA specifies particular dosages determined to be safe and effective for each indication.

35. The indication and dosages approved by FDA are set forth in the drug's labeling, the content of which is also closely reviewed by FDA. 21 U.S.C. §§ 352, 355(d). An example of the drug's labeling is the printed insert in the drug's packaging. FDA approves the NDA only if the labeling conforms to the uses and dosages that FDA has approved. 21 U.S.C. § 355(d).

36. Under the FDAMA, if a company wishes to market or promote an approved drug for additional uses – *i.e.*, uses not listed on the approved label – the company must perform additional clinical trials similar to those which supported the initial approval, and then submit a supplemental NDA, or "sNDA." 21 U.S.C. § 360aaa(b), (c). Until FDA approval of the new indication or dose, it is off-label and cannot be the subject of marketing efforts. Off-label marketing restrictions are an

important patient-safety feature of the FDAMA because these restrictions maintain a company's incentive to engage in appropriate testing and apply for additional indications rather than skirt FDA review.

37. "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than the indications approved by FDA and described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population (e.g., treating a child when the drug is approved to treat adults).

38. Although FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, it does not regulate the practice of medicine.

39. Although physicians may prescribe drugs for off-label usage, the law prohibits drug companies from marketing or promoting a drug for a use that FDA has not approved, or for a patient group FDA has not approved. A company illegally misbrands a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by FDA. 21 U.S.C. §§ 331, 352.

40. In addition to prohibiting drug companies from directly marketing and promoting a drug's unapproved use, Congress and FDA have also sought to prevent drug companies from employing indirect methods to accomplish the same end. For example, FDA regulates two of the most prevalent indirect promotional strategies: (1) dissemination of medical and scientific publications concerning the off-label uses of

their products; and (2) support for Continuing Medical Education ("CME") programs that focus on off-label uses.

41. With regard to the first practice – disseminating written information – the FDAMA prohibits drug companies from disseminating information regarding off-label usage unless it receives an "unsolicited request from a health care practitioner." 21 U.S.C. § 360aaa-6. In any other circumstance, a company may not disseminate information concerning the off-label uses of a drug unless it has submitted an application to FDA seeking approval of the drug for the off-label use; has provided the materials to FDA prior to dissemination; and the materials themselves are submitted in unabridged form and are neither false nor misleading. 21 U.S.C. §§ 360aaa(b) & (c); 360aaa-1.

42. The off-label regulatory regime protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body, FDA.

43. While FDA has authority to enforce compliance with its advertising and promotional restrictions for the purpose of protecting the public, it has no authority to redress violations by drug companies, whether to protect government healthcare programs against false claims or remedy such claims already submitted.

C. The Anti-Kickback Statute.

44. Under the Medicare and Medicaid Patient Protection Act, 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute" or "AKS"), it is unlawful to knowingly offer or pay any remuneration in cash or in kind in exchange for the referral of any product for which payment is sought from any government healthcare program, including Medicare,

Medicaid, and TRICARE. Violation of the statute can subject the perpetrator to criminal and civil penalties, as well as exclusion from participation in government healthcare programs.

45. The AKS also provides that claims arising out of violations of its provisions are false claims. A claim "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim" for purposes of the False Claims Act. 42 U.S.C § 1320a-7b(g).

46. The AKS is designed to, *inter alia*, ensure that patient care will not be improperly influenced and corrupted by compensation arrangements which are not directly related to the care of patients or which influence patient care decisions.

47. Payment of remuneration of any kind violates the statute if one of the purposes of the payment is to induce referrals, and remuneration offered or paid in return for the promise to send patients to a particular provider or facility qualifies as a kickback. Giving a person the opportunity to earn money for referring patients may also constitute an inducement under the AKS.

48. Government healthcare programs require every provider who seeks payment to sign agreements with the United States in order to establish their eligibility to seek reimbursement. Every provider described in this complaint signed an agreement with the United States certifying that:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations, and program instructions are available through the [Medicare] contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal Anti-Kickback Statute and

> the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.
>
> Form CMS-855.

49. Compliance with the AKS is a condition of payment for all claims submitted for reimbursement by Medicaid, Medicare, and other government healthcare programs.

D. Prescription Drug Payment Under Government Healthcare Programs.

1. <u>The Medicaid Program</u>.

50. Medicaid is a public assistance program providing for payment of medical expenses for approximately 55 million low-income patients. Funding for Medicaid is shared between the federal government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

51. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs." 42 U.S.C. §§ 1396b(I)(10), 1396r-8(k)(2), (3).

52. Under the Medicaid statute, a "covered outpatient drug" includes a drug dispensed by prescription and approved as safe and effective under the FDCA, 21 U.S.C. §§ 355 & 357, but does not include "a drug or biological used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(2), (3).

53. The statute defines "medically accepted indication" as:

> any use for a covered outpatient drug which is approved under the [FDCA], or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.

Id. at § 1396r-8(k)(6). The three compendia described in subsection (g)(1)(B)(i) are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information (and its successor publications), and the Drugdex Information System. *Id*. at § 1396r-8(g)(1)(B)(i).

54. In addition to on-label uses, whether an FDA-approved drug is listed in one or more of these three compendia for a particular indication determines whether a prescription for that use may be reimbursed under Medicare and Medicaid and other government healthcare programs.

55. In order to participate in the Medicaid program, a State must have a plan for medical assistance that has been approved by the CMS, which administers the program on behalf of the Secretary of Health and Human Services. The state plan must specify, among other things, the specific kinds of medical care and services that will be covered. 42 U.S.C. § 1396a(a)(10), (17). If the plan is approved by the Secretary, the State thereafter is eligible for federal financial participation, i.e., reimbursement by the federal government for a specified percentage of the amounts that qualify as medical assistance under the state plan. *Id*. at §§ 1396b(a)(1), 1396d(b).

56. States are accorded broad flexibility in tailoring the scope and coverage of their plans. While the Medicaid Act requires States to provide certain basic services, the Act permits, but does not require, States to cover prescription drugs, although most States choose to do so. 42 U.S.C. § 1396d(a)(12).

57. In 1990, Congress enacted the Medicaid Drug Rebate Statute, codified at 42 U.S.C. §1396r-8, to "establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug

to any public or private purchaser." H.R. Rep. No. 881, 101st Cong., 2d Sess. 96 (1990). That statute prohibits federal financial participation for covered outpatient drugs unless there is a rebate agreement in effect under section 1396r-8. 42 U.S.C. §§ 1396b(i)(10)(A) and 1396r-8(a)(1).

58. Once a drug company has entered into a rebate agreement for a covered outpatient drug, a State is generally required to cover that drug under the state plan. However, there are several provisions of the Medicaid Act that permit a State to exclude or restrict coverage. 42 U.S.C. § 1396a(a)(54); H.R. Rep. No. 881 at 97, 98.

59. A State may exclude or restrict coverage of a drug where "the prescribed use is not for a medically accepted indication," *i.e.*, a use which is not listed in the labeling approved by FDA, or which is not included in one of the drug compendia identified in the Medicaid statute. 42 U.S.C. § 1396r-8(k)(6); § 1396r-8(d)(1)(B)(i). Most states restrict coverage of drugs in accord with the Social Security Act, including the federal restrictions on medically-accepted indications.

60. State Medicaid agencies administer Medicaid and reimburse pharmacies for drugs, which submit claims on behalf of individual Medicaid beneficiaries. The State agencies in turn submit claims to the United States for the federal financial participation of claims submitted on behalf of Medicaid beneficiaries.

61. Medicaid claims, depending on the circumstances, may be submitted by pharmacies electronically or on paper, but in most cases use a standard Form, such as the CMS-Form 1500, or other similar claim form (in Florida, for example, a "Universal Claim Form" is used) which records, among other things, the identity of the beneficiary, the provider, and the drug.

62. Drugs are identified on Medicaid claims and the Medicaid computer system drug file by the National Drug Code ("NDC"). The NDC is an 11-digit number. The first 5 digits identify the manufacturer or supplier, the next 4 digits identify the product, and the last 2 digits identify the package size.

2. The Medicare Program.

63. The Medicare Prescription Drug Improvement and Modernization Act of 2003 added prescription drug benefits to the Medicare program. Medicare serves approximately 43 million elderly and disabled Americans.

64. The first stage of the Medicare program, from May 2004 through December 2005, permitted Medicare beneficiaries to enroll in a Medicare-approved drug discount card program.

65. In addition, low-income beneficiaries, defined as those whose incomes are not more than 135% of the poverty line (those with incomes of no more than $12,569 for a single person or $16,862 for a married couple in 2004) qualified for a $600 credit (funded by Medicare) on their drug discount card for 2004 and again for 2005.

66. Starting in January 2006, Part D of the Medicare Program provided subsidized drug coverage for all beneficiaries, with low-income individuals receiving the greatest subsidies.

67. For those beneficiaries with dual eligibility under both Medicare and Medicaid, their prescription drugs are covered exclusively under Medicare Part D. Thus, the responsibility for providing pharmacy benefits for dually eligible beneficiaries was transferred from Medicaid to Medicare Part D on January 1, 2006.

68. The Part D prescription drug program provides comparable benefits and exclusions as the Medicaid program.

69. Specifically, a Part D covered drug is available only by prescription, if approved by FDA (or is a drug described under section 1927(k)(2)(A)(ii) or (iii) of the Social Security Act), used and sold in the United States, and used for a medically accepted indication (as defined in section 1927(k)(6) of the Act). A covered Part D drug includes, *inter alia*, prescription drugs.

70. The definition of a covered Part D drug specifically excludes drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under section 1927(d)(2) of the Act, with the exception of smoking cessation agents.

71. Medicare Part D is administered through CMS, with coverage provided through private drug plans. Plan sponsors are authorized to negotiate independently pharmacy reimbursement and price concessions with drug companies and pharmacies, and then to seek reimbursement from Medicare.

72. All plan sponsors are required to have a comprehensive plan to detect, correct and prevent fraud, waste and abuse. The specific requirements of the compliance program for the Part D benefit includes directions to specific kinds of fraud and abuse in violation of program requirements, such as non-compendia drug payments.

73. For example, the Prescription Drug Benefit Manual ("PDBM") issued by CMS identifies an example of Sponsor fraud, waste and abuse as "Non-compendia payments: Payments for Part D drugs that are not for a ‘medically accepted

indication.'" PDBM, Ch. 9, § 70.1.1. The PDBM further specifically identifies an example of pharmaceutical company fraud, waste and abuse as "Illegal Off-Label Promotion: Illegal promotion of off-label drug usage through marketing, financial incentives, or other promotional campaigns." PDBM, Ch. 9, § 70.1.6.

74. Medicare may also pay for prescription drugs for inpatients through other parts of the program, but does not pay for non-medically indicated drugs under any aspect of its prescription drug coverage.

3. Reimbursement Under Other Government Healthcare Programs.

75. In addition to Medicaid and Medicare, the federal government reimburses a portion of the cost of prescription drugs under several other government healthcare programs, including but not limited to, CHAMPUS/TRICARE/CHAMPVA, the Federal Employees Health Benefit Program, the Indian Health Service, and the Railroad Retirement Medicare Program.

76. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a healthcare program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veterans Affairs, is a healthcare program for the families of veterans with 100 percent service-connected disabilities. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors. The Indian Health Service, administered by the Department of Health and Human Services, provides health services to Native Americans. The Railroad Retirement Medicare program,

administered through the United States Railroad Retirement Board, provides Medicare coverage to retired railroad employees.

77. Coverage for off-label prescription drugs under these programs is similar to coverage under the Medicaid program, consistent with the regulatory framework under the FDCA. *E.g.*, 32 C.F.R. Part 199; TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B)(2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

78. Reimbursement for drugs under these programs may occur either through direct purchase of drugs later administered at government facilities or through coverage of drugs administered by other providers to veterans and members of the armed forces eligible for benefits under these programs.

E. Claims Caused to Be Submitted For Off-Label Non-Compendium Usage Of Abilify Are False Claims.

79. As a condition of payment of Medicare, Medicaid and other government healthcare programs, claims can be submitted only for "covered outpatient drugs," that are the subject of a rebate agreement with a pharmaceutical company. To be covered, drugs must be used for a medically-accepted indication, including a use approved by its label or approved by published compendia authorized by the Medicaid statute.

80. Because those programs specifically exclude coverage and reimbursement for off-label non-compendia uses of drugs, claims submitted for such drugs prescribed for such uses violate statutory pre-conditions of payment.

81. Claims submitted to government healthcare programs in violation of conditions of payment are false claims. Submission of such claims materially

misrepresents that the claims are eligible for reimbursement consistent with applicable statutes and regulations, and results in the payment disbursement of public funds never intended to be used for that purpose.

82. Defendants' violations would have affected the Government's decision to pay the claims.

83. As alleged below, Defendants illegally marketed and promoted Abilify for off-label, non-compendia use. The off-label uses of Abilify were neither approved by FDA nor included in any of the drug compendia specified by the Medicaid statute. Rather, indications listed on the FDA-approved label and the authorized compendia for Abilify are identical.

84. As a result of Defendants' illegal marketing campaign, claims have been submitted for Abilify in material violation of conditions of payment of the claims.

85. Defendants' illegal actions were the substantial factor in causing the submission of claims in violation of known conditions of payment.

86. Defendants' illegal off-label marketing campaign was the driving factor causing the submissions for reimbursement for Abilify to Medicare, Medicaid and other healthcare programs for non-reimbursable uses.

87. Thus, every claim which Defendants caused to be submitted for non-medically-indicated uses of Abilify is a false claim. Defendants' knowing conduct in causing the submission of such claims violated the False Claims Act.

F. Corporate Integrity Agreement Between the United States and BMS.

88. BMS has long been aware that its illegal actions caused false claims for Abilify to be submitted to Medicare, Medicaid, and other government

healthcare programs. In addition to its obligation to know and to comply with the law in order for its drugs to be covered by those programs, BMS entered into an agreement with the United States to police and certify its ongoing compliance with those laws as a condition of continued participation in such programs.

89. In September 2007, BMS entered into a five-year Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("the 2007 CIA").

90. In the 2007 CIA, BMS promised the United States that it would establish and maintain a compliance program, develop and implement a business code of conduct for all employees, and ensure its policies and procedures addressed, among other things:

- appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b), and the False Claims Act (codified at 31 U.S.C. 3729-3733);

- appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all FDA requirements, including procedures governing the handling and/or response by sales representatives, Medical Science Liaisons, and Medical Information to requests for information about off-label uses;

- appropriate mechanisms by which the Medical Information Department receives and responds to requests for information about off-label uses of BMS's products, including but not limited to, the form and content of information disseminated by Medical Information in response to such requests and the internal review process for the information disseminated;

- ***call plan development for the Group's sales representatives for those Government Reimbursed Products having a high potential for off-label use that could be driven by detailing an inappropriate audience of HCPs [healthcare professionals] or institutions. For each such product, the Policies and Procedures shall require that BMS review the associated call plans and the bases upon which physician***

specialties and institutional provider types are included in, or excluded from, the call plans. The Policies and Procedures shall also require that BMS shall modify the call plans as necessary to ensure that BMS is promoting its products in a manner that complies with all applicable Federal health care program and FDA requirements. The call plan reviews shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a product meeting the requirements set forth above;

- consultant engagements entered into with HCPs (including, but not limited to, those engagements relating to speaker programs, speaker trainings, advisory boards, or any similar fee- for-service relationship with an HCP) and all events and expenses relating to such HCP engagements. These policies shall be designed to ensure that the consultant engagements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements; and

- Policies and Procedures relating to incentive compensation for Covered Persons who are sales representatives that are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of BMS's products.

2007 CIA, pp.9-12, Section B.3, (emphasis supplied).

91. Thus, pursuant to the CIA, BMS agreed to ensure that no further off-label promotion of Abilify occurred, including by agreeing to review its call lists and the bases upon which physician specialties and institutional provider types were included in, or excluded from, those lists. 2007 CIA, p. 10, Section III.B.3.f. In exchange for this agreement about their future conduct, the United States agreed to settle claims against BMS for its pre-2005 conduct in violation of off-label-promotion prohibitions.

92. BMS agreed to modify its call lists as necessary to ensure that it was promoting its products in a manner that complied with all applicable Federal health care program and FDA requirements; and BMS's call list review would occur at least annually and each time FDA approved a new or additional indication for Abilify. 2007 CIA, p.10, Section III.B.3.f.

93. In the 2007 CIA, BMS squarely promised the United States that it would prohibit sales representatives from marketing Abilify to children or adolescent providers for the treatment of MDD—an indication never approved for children or adolescents. The 2007 CIA also flatly prohibits Abilify sales representatives from targeting their marketing efforts to a population comprised largely of elderly patients with dementia, given that Abilify contains a Black Box warning for the treatment of such patients.

94. The 2007 CIA also contains detailed training and independent review requirements regarding BMS policies and procedures.

95. The 2007 CIA requires BMS to establish a Disclosure Program for its employees that includes a mechanism (a toll-free compliance telephone line) to enable individuals to disclose, to the Chief Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with BMS's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. This Program is required to emphasize a nonretaliation policy. 2007 CIA, p.20, Section E.

96. The 2007 CIA requires BMS to retain a surveying entity to review its detailing records, and to provide that information as part of an annual report to the OIG. 2007 CIA, p.25, Section J.

97. The 2007 CIA requires that the BMS Compliance Department has developed a Field Force Monitoring Program (FFMP) to evaluate and monitor US Pharmaceuticals Group sales representatives' interactions with HCPs. The FFMP is a

formalized process designed to directly observe the appropriateness of sales representative interactions with HCPs and to identify potential off-label promotional activities. BMS compliance personnel were to conduct field observations of sales representatives to assess whether the messages delivered and materials distributed to HCPs are consistent with BMS compliance Policies and Procedures. This requirement provides for formal investigation of any identification of potential off-label promotion, and inclusion of such information in its annual reports to the OIG. 2007 CIA, pp.31-32, Section M.

98. BMS's annual reports to the OIG contained certifications by its Chief Compliance Officer that it is in compliance with the terms of the CIA and, among other things, that "BMS's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside BMS … are in compliance with the requirements of the Federal anti-kickback statute, the Prescription Drug Marketing Act, and other applicable laws and legal requirements." 2007 CIA, p. 39-40, Section C.

99. In the annual report, BMS also specifically certified that (i) its call plans for those Government Reimbursed Products subject to the requirements of the CIA were reviewed by BMS's internal U.S. Healthcare Law Compliance at least once during the Reporting Period (consistent with the requirements of Section III.B.3.f of the CIA) and, (ii) for each such Government Reimbursed Product, the call plans were found to be consistent with BMS's policy objectives as referenced above in Section III.B.3.f. *Id.* The call plans to be reviewed and approved by BMS's internal U.S. Healthcare Law Compliance included the physicians to be targeted by BMS's sales force, and the bases

upon which physician specialties and institutional provider types were included in, or excluded from, these call plans. *Id.* at Section III.B.3.f.

100. BMS agreed to the 2007 CIA as part of the settlement of a *qui tam* action alleging that BMS violated the FCA by marketing and promoting Abilify for off-label use, thereby causing false claims for such use to be submitted to government healthcare programs.

101. In the settlement of that case, also dated September 2007, the United States released its claims against BMS for the following Covered Conduct:

> The Government contends that, during the period from January 2002 through December 2005, BMS knowingly promoted the sale and use of Abilify (aripiprazole) for pediatric use (i.e., for patients younger than 18) and to treat dementia-related psychosis, uses for which the United States Food and Drug Administration ("FDA") has not approved Abilify. The Government contends that BMS knowingly and willfully offered and paid illegal remuneration in the form of consulting arrangement fees to physicians to prescribe Abilify. The Government contends that BMS's promotion of Abilify for pediatric use and to treat dementia-related psychosis violated the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a) & (d). Furthermore, the Government contends that, during the relevant time period, these uses were not medically-accepted indications, as defined by 42 U.S.C. § 1396r-8(k)(6) (uses approved under the FDCA or included in or approved for inclusion in specified drug compendia), and that certain State Medicaid Programs did not cover Abilify dispensed for these uses. In addition, the Government contends that, during this time period, BMS knowingly caused false and/or fraudulent claims to be submitted to Medicaid, TRICARE, and FEHBP for Abilify, and caused the DVA and DOD to purchase Abilify, for pediatric use and for dementia-related psychosis.

Settlement Agreement, ¶ N.4.

102. The United States further released the claim that:

> during the period from January 1999 through December 2003, BMS knowingly and willfully offered and paid illegal remuneration to physicians, and to some physician assistants and nurse

> practitioners, through consulting fees and expenses for participating in National Consulting Conferences, Regional Consulting Conferences, Clinical Advisory Councils, District Advisory Boards, Interactive Training Sessions, Preceptorships, and similar consulting programs, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2). The Government further contends that, during this time period, BMS knowingly caused the submission of false and/or fraudulent claims to Medicaid, Medicare, other federal health care programs, and caused DVA and the Department of Defense ("DOD") to purchase BMS drugs, by inducing these physicians, physician assistants, and nurse practitioners to prescribe and/or to recommend the prescribing of the BMS drugs listed in Attachment B [listing Abilify].

Settlement Agreement, ¶ N.3.

103. Notwithstanding this settlement and its ongoing obligations under the CIA, BMS continued to illegally promote Abilify for off-label uses and has done so continuously since the end of the Covered Conduct time frame (2005) and going forward.

104. BMS's false certifications to the United States contributed to the material misrepresentations made to the United States regarding the reimbursement for off-label, non-compendia uses of Abilify, in violation of conditions of payment for federal and state healthcare programs.

105. BMS's false statements caused false claims to be paid or approved by Medicare, Medicaid and other government healthcare programs in violation of the FCA.

G. The Corporate Integrity Agreement Between the United States and Otsuka.

106. Similarly, Otsuka has long been aware that its illegal actions caused false claims for Abilify to be submitted to Medicare, Medicaid, and other government healthcare programs. In addition to its obligation to know and to comply

with the law in order for its drugs to be covered by those programs, Otsuka entered into an Agreement with the United States to police and certify its ongoing compliance with those laws as a condition of continued participation in such programs.

107. In March 2008, Otsuka entered into a five-year Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("the 2008 CIA").

108. In the 2008 CIA, Otsuka promised the United States that it would establish and maintain a compliance program, develop and implement a business code of conduct for all employees, and ensure its policies and procedures addressed, among other things:

- appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b), and the False Claims Act (codified at 31 U.S.C. 3729-3733);

- appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all FDA requirements, including procedures governing the handling and/or response by sales representatives, Medical Science Liaisons, and Medical Information to requests for information about non-FDA approved (off-label) uses;

- the mechanisms through and manner in which Otsuka receives and responds to requests for information about off-label uses of Otsuka's products; the form and content of information disseminated by Otsuka in response to such requests and the internal review process for the information disseminated.

- development of sales call plans for Government Reimbursed Products. ***For each product, the Policies and Procedures shall require that Otsuka review the call plans for the product and the bases upon which specified physician specialties and institutional provider types are included in, or excluded from, the call plans. The Policies and Procedures shall also require that Otsuka modify the call plans as necessary to ensure that Otsuka is promoting its products in a manner that complies with all applicable Federal health care program***

and FDA requirements. The call plan reviews shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a Government Reimbursed Product;

- consultant engagements or fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to, speaker programs, speaker trainings, advisory boards, or any similar relationship with an HCP or HCI) and all events and expenses relating to such engagements or arrangements. These policies shall be designed to ensure that the engagements or arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements; and

- compensation (including salaries and bonuses) for Covered Persons. These Policies and Procedures shall be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Otsuka's products.

2008 CIA, pp.5-8 Section III.B.2, (emphasis supplied).

109. Thus, pursuant to the CIA, Otsuka agreed to ensure that no further off-label promotion of Abilify occurred, including by agreeing to review its call lists and the bases upon which physician specialties and institutional provider types were included in, or excluded from, those lists. 2008 CIA, p. 7, Section III.B.2.e. In exchange for this agreement about its future conduct, the United States agreed to settle claims against Otsuka for its pre-2005 conduct in violation of off-label-promotion prohibitions.

110. Otsuka agreed to modify its call lists as necessary to ensure that it was promoting their products in a manner that complied with all applicable Federal health care program and FDA requirements; and Otsuka's call list review would occur at least annually and each time FDA approved a new or additional indication for Abilify. 2008 CIA, p.7 Section III.B.2.e.

111. The 2008 CIA flatly prohibits sales representatives from marketing Abilify to children or adolescent providers for treatment of MDD—an indication never

approved for children or adolescents. The 2008 CIA also flatly prohibits Abilify sales representatives from targeting their marketing efforts to a population comprised largely of patients with dementia, given that Abilify contains a Black Box warning for treatment of such patients.

112. The 2008 CIA also contained detailed training and independent review requirements regarding Otsuka policies and procedures.

113. The 2008 CIA required Otsuka to establish a Disclosure Program for its employees that includes a mechanism (a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Otsuka's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. This Program was required to emphasize a nonretaliation policy. 2008 CIA, p.15, Section E.

114. The 2008 CIA required Otsuka to engage one or more OIG-approved Independent Review Organizations ("IRO"), such as an accounting, auditing, or consulting firms, to perform reviews to assist in assessing and evaluating Promotional and Product Services Related Functions. The IRO was to conduct reviews that assess Otsuka's systems, processes, policies, procedures, and practices relating to Promotional and Product Services Related Functions. The IRO and Otsuka were to retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Otsuka) related to the reviews. 2008 CIA, p. 12, Section D(1)(a)-(c); Appendix A.

115. The 2008 CIA required that Otsuka continue with its Field Force Monitoring Program (FFMP), developed to evaluate and monitor sales representatives' interactions with HCPs. The FFMP is a formalized process designed to directly observe the appropriateness of sales representative interactions with HCPs and to identify potential off-label promotional activities. The FFMP required that Otsuka District Managers conduct field observations of all sales representatives to assess whether targeted physicians treat patients with approved indications for the Otsuka product. If not, the District Manager was to notify the Compliance Officer and the Vice President for Sales and request that the physician be removed from the call list, and was to instruct the sales representative to discontinue calling on the physician. This requirement provided for formal investigation of any identification of potential off-label promotion, and inclusion of such information in its annual reports to the OIG. 2008 CIA, pp.19-20, Section J.

116. Otsuka's annual reports to the OIG contained certifications by its Compliance Officer that it was in compliance with the requirements of the CIA and, among other things that "Otsuka's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside Otsuka … are in compliance with the requirements of the Federal anti-kickback statute, the Prescription Drug Marketing Act, and other applicable laws and legal requirements." 2008 CIA, p. 26, Section C.

117. In the annual report, Otsuka also specifically certified that its call plans for those Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with the requirements of Section III.B.2.e of the CIA)

and, the call plans were found to be consistent with Otsuka's policy objectives as referenced above in Section III.B.2.e. *Id.* The call plans to be reviewed and approved included the physicians to be targeted by Otsuka's sales force, and the bases upon which physician specialties and institutional provider types were included in, or excluded from, these call plans. *See id.*

118. Under the CIA, a material breach of the CIA by Otsuka constitutes an independent basis for Otsuka's exclusion from participation in the Federal health care programs. 2008 CIA, p.32.

119. Otsuka agreed to the 2008 CIA as part of the settlement of a *qui tam* action alleging that Otsuka violated the FCA by marketing and promoting Abilify for off-label use, thereby causing false claims for such use to be submitted to government healthcare programs. Notwithstanding this settlement and its ongoing obligations under the CIA, Otsuka continued to illegally promote Abilify for off-label uses and has done so continuously since the end of 2005 and going forward.

120. Otsuka's false certifications to the United States contributed to the material misrepresentations made to the United States regarding the reimbursement for off-label, non-compendia uses of Abilify, in violation of conditions of payment for government healthcare programs.

121. Otsuka's false statements caused false claims to be paid or approved by Medicare, Medicaid and other government healthcare programs in violation of the FCA.

H. FDA-Approved Indications and Warnings for Abilify.

1. Adult Indications.

122. Abilify (aripiprazole) is an atypical antipsychotic drug. In November 2002, FDA approved labeling indicating Abilify for treatment of Schizophrenia in adults.

123. In September 2004, FDA approved an indication for Abilify for treatment of acute manic and mixed episodes associated with Bipolar I Disorder in adults. Abilify has never been approved for the treatment of Bipolar depression.

124. In November 2007, FDA approved labeling for Abilify indicating it as an adjunctive treatment for Major Depressive Disorder ("MDD") in adults. The phrase "adjunctive treatment" refers to the use of an additional medication to supplement an existing therapeutic regimen.

2. Child and Pediatric Indications and Warnings.

125. In October 2007, FDA approved labeling for Abilify indicating the drug for treatment of Schizophrenia in adolescents 13 to 17 years of age. This was the drug's first pediatric indication.

126. In November of 2007, FDA required Defendants to include the following Black Box warning with respect to the use of Abilify with pediatric patients:

Children, adolescents, and young adults taking antidepressants for Major Depressive Disorder (MDD) and other psychiatric disorders are at increased risk of suicidal thinking and behavior.

127. In February 2008, FDA approved labeling for Abilify indicating it for treatment of acute manic and mixed episodes associated with Bipolar I Disorder in pediatric patients 10-17 years of age.

128. In November 2009, FDA approved labeling for Abilify indicating it for treatment of irritability associated with autistic disorder for pediatric patients aged 6-17 years.

129. Underscoring the limited nature of the pediatric indications for Abilify and the risks attendant to its use by pediatric patients with depression, the 2009 label includes the express warning in the detailed Black Box warning that "Abilify is not approved for use in pediatric patients with depression."

3. Absence of Elderly Indications, Presence of Warnings.

130. FDA has issued Black Box warnings guarding against the use of Abilify in elderly patients.

131. Indeed, not only is there no specific indication for use in the geriatric population, but Defendants' studies did not evaluate the use of Abilify for geriatrics: the placebo-controlled studies of the use of Abilify in patients with Schizophrenia, Bipolar mania, and MDD "did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects." In fact, the inclusion criteria for the clinical trial specific to the MDD indication, published in 2008 as "The Efficacy and Safety of [Abilify] as Adjunctive Therapy in Major Depressive Disorder," were outpatients aged 18-65 years old. Anyone older than 65 was expressly excluded from the study. Simply put, Defendants' studies did not contain a sufficient number of elderly subjects in order to make a determination of the safety and efficacy of the drug in the elderly.

132. In April 2005, FDA issued a Public Health Advisory that it had determined that increased mortality was associated with the use of atypical second

generation anti-psychotic medications, including Abilify, for behavioral disorders in elderly patients with dementia.

133. In February 2006, FDA required the inclusion of a Black Box warning on the label, advising that Abilify had been associated with "INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS."

134. In November 2007, when FDA modified Abilify's required Black Box warning to include a warning aimed at children, adolescents, and young adults, FDA required Abilify to retain the warning that Abilify had been associated with "INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS. The warning provided:

> Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. ABILIFY is not approved for the treatment of patients with dementia-related psychosis.

135. In 2008, FDA required new safety information to be included in relation to the warning regarding increased mortality in elderly patients with dementia-related psychosis. Abilify's new label was to include more detailed information regarding the trials supporting the warning that elderly patients with dementia-related psychosis on Abilify are at an increased risk of death. The label added, for example: "Although the causes of death were varied, most of the deaths appeared to be either cardiovascular, e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature."

136. Thus, from 2005 through October 2007, the only approved labeling for Abilify was for the treatment of Schizophrenia and acute manic and mixed episodes associated with Bipolar I Disorder in adults. In November 2007, an additional indication was received for adjunctive treatment of MDD in adults. The only approved indications

for adolescent and pediatric patients were after October 2007, and were limited to the treatment of Schizophrenia in adolescents; the treatment of acute manic and mixed episodes associated with Bipolar I Disorder in patients ages 10-17; and irritability associated with autistic disorder for patients ages 6-17.

VI. ALLEGATIONS OF FACT.

A. Corporate Policies and Practices: Defendants Worked in Concert to Illegally Market Abilify.

137. In approximately 1999, Otsuka and BMS entered into an agreement to co-develop and co-promote sales of Abilify worldwide. Under that agreement, BMS purchased the product from Otsuka, performed the finish manufacturing for sale, and was responsible for the invoicing of all third-party customers. BMS and Otsuka shared in the revenue recognized by BMS for the net sales of Abilify, pursuant to contractually-recognized shares. For Abilify sold in the U.S., BMS recognized more than 50% share of the net sales, pursuant to its co-promotion agreement with Otsuka.

138. As detailed below, Defendants BMS and Otsuka implemented a marketing strategy to work in concert to improperly co-promote Abilify for off-label use.

139. Despite the fact that both Defendants entered into Corporate Integrity Agreements with the United States to resolve allegations regarding off-label promotion of Abilify from 2002 through 2005, Defendants blatantly continued their illegal marketing strategy.

140. Defendants formed sales teams to work together in their widespread targeting of providers to prescribe Abilify for off-label uses, including by promoting Abilify for off-label uses to providers of child and adolescent patients, and geriatric care patients, and by marketing its use for diagnoses which are not medically-

indicated by its label. In so doing, Defendants directed their sales teams to continue to target the physicians that Defendants had agreed, via the Corporate Integrity Agreements, not to contact with indications inappropriate for their patient population.

141. When BMS began its marketing of Abilify in 2002, its sales force was divided into (i) a Long Term Care division ("LTC"), which focused on nursing and residential home sales, and hospital geriatric psychiatric units; (ii) Office-Based Sales ("OBS"), which focused on retail sales to private practices; and (iii) Institutional Sales Specialists ("ISS"), which focused on hospital adult psychiatric units.

142. In 2005, BMS changed the name of the LTC division to Residential Care ("RCC"). Although the name changed, the focus of the division remained the same—facility-based sales—and no changes were made to the group's call lists. Abilify's only FDA-approved indications in 2005 were for manic and mixed episodes associated with Bipolar I Disorder, and Schizophrenia, in adults only. The lack of safety and efficacy data with respect to the elderly, as well as the dangers associated with prescribing Abilify for use in the elderly, were certainly known at this time. OBS continued to sell to private psychiatric practices.

143. In October 2007, in anticipation of FDA-approved indication for MDD for adults, the RCC and ISS divisions were merged into a new Account-Based Sales ("ABS") division, which focused on sales to nursing homes, hospitals, including children's hospitals, and other facilities. The other Neuroscience division, OBS, continued to focus on retail sales to office-based psychiatrists.

144. Pursuant to their agreement, Defendants co-promoted the drug, each with assigned representatives in defined sales territories. The Otsuka

representatives marketed mainly to office-based providers, rather than institutional providers, but they had “total dirt.” This meant that they were allowed to sample and call on any provider they thought would move Abilify, irrespective of specialty or location, and they received credit for all sales in their geographic region, not just those related to specific providers. Otsuka representatives participated in the BMS-run sales teams, and collaborated closely with BMS on shared targets. Targeted providers thus received multiple calls from BMS and Otsuka sales representatives assigned to overlapping territories, who were each required to call on the targets on their call lists a certain number of times within a month.

145. BMS generated call lists for sales teams, called "pods", led by BMS, which contained both BMS representatives and the Otsuka counterparts for that territory. BMS sales representatives worked with Otsuka counterparts, who regularly attended BMS sales strategy meetings, and received BMS instructions and promotional materials. The team members often shared weekly updates regarding their coverage area and targets with each other. BMS and Otsuka management also attended regular strategy meetings together, as well as quarterly and national sales meetings. Otsuka representatives, however, called not just on the targets in BMS sales plans, but also called on a range of other targets, without regard to the appropriateness of the target or the sales message.

146. In October 2009, BMS reorganized its Neuroscience division sales force again, this time into OBS and PFS, the latter focusing only on pediatric sales. The electronic system for sharing call lists and call notes, and tracking sales, was changed at that time from "Call Max" to "Navigator" and became a shared system between BMS

and Otsuka sales representatives. The sales representatives from BMS and Otsuka still participated in pods, but used the same software (Navigator) to track and document sales efforts, and had shared access to call notes, leading to more open collaboration between BMS and Otsuka. As part of this reorganization, many BMS sales representatives were terminated and then hired by Otsuka.

147. Both BMS and Otsuka sales forces were incentivized by a volume-based compensation system to call on providers and increase prescribing habits, without regard to appropriateness of the targets or the message. Beginning in 2007 and continuing throughout the term of Relators' employment, BMS sales representatives were compensated based on Sale and Call Attainment scores ("SAS/CAS"). The SAS measured the percentage of required targets actually called on, and the CAS measured the percentage of required calls made on specified targets. Representatives were rated on their ability to contact the targets provided by Defendants via the call lists and on the frequency of calls to those targets. Representatives who did not attain the required SAS/CAS scores would not get a raise, would not get a bonus, and would be targeted for termination. On information and belief, Otsuka representatives were compensated via a similar structure.

148. To further illustrate the ways in which Defendants worked in concert, when Relator Ibanez was an RCC sales representative from 2005 to 2007, Otsuka representatives Jeff Schneider and Alex Fischer were assigned to the same territory as Relator Ibanez. Mr. Schneider worked in the Dayton and northern Cincinnati, Ohio area, and Mr. Fisher worked in the Cincinnati, Ohio and northern Kentucky area. Prior to Abilify obtaining any child or adolescent-approved indications in

October 2007, BMS and Otsuka sales teams made calls on child and adolescent psychiatrists. When Relator Ibanez became an ABS representative in late 2007, the same Otsuka representatives were assigned to overlapping territory. Relator Ibanez continued to work with Mr. Schneider until January 2009, and with Mr. Fisher until July 2010. Relator Ibanez observed that both Mr. Schneider's and Mr. Fisher's call lists contained providers who treated patient classes for whom there were no approved indications. In 2009, for example, when BMS's and Otsuka's databases were integrated, Relator Ibanez learned that he and Mr. Fisher received identical target lists, which continued to include providers who treated unapproved patient classes.

149. Throughout his time at BMS, Relator Ibanez observed field-level sharing of data between BMS and Otsuka, as well as shared call lists, quarterly management strategy sessions and weekly pod meetings between representatives. He learned from his Regional Business Director Steve Mahle that Otsuka kept a strict watch over the BMS sales organization, including the number of BMS representatives in the field, the number of territories BMS targeted, and the number of calls made. Changes in the sales organization had to be approved by Otsuka, as Relator Ibanez understood that BMS was contractually required by Otsuka to keep to certain quotas in its sales coverage of Abilify.

150. Similarly, Relator Edwards observed that both Defendants were heavily involved in the planning of Abilify marketing strategy. BMS and Otsuka sales representatives openly shared territory and target lists.

151. For example, Relator Edwards worked with two Otsuka representatives from 2005 to 2007. In 2006, Relator Edwards attended a state planning

meeting for her territory that included both BMS and Otsuka management. Between March 2008 and October 2009, Otsuka sales representative Shauna Eginton attended at least ten joint sales presentations and luncheons scheduled by Relator Edwards. Ms. Eginton, a member of Relator Edwards's team, was regularly apprised of BMS sales efforts and provided her own updates in return. Ms. Eginton and other Otsuka counterparts (including, for example, Anna Marie Mars), also shared in the logistics and planning of marketing programs. Among other shared efforts, Otsuka and BMS sales representatives took turns coordinating speaker lunch and dinner events, including sending out invitations that contained the names of both Otsuka and BMS sales members.

152. In 2012, Defendants' co-promotion agreement came to an end, and Otsuka took over all marketing of Abilify. With the termination of the agreement, BMS eliminated all of its Abilify sales and medical representative positions, which comprised nearly 500 people. Many of those who were laid off by BMS were hired on by Otsuka.

153. As described in more detail in the sections that follow, this joint off-label promotion of Abilify by Defendants caused the submission of false claims to government-insured healthcare programs in violation of federal and state False Claims Acts, as detailed below.

B. Illegal Off-Label Promotion of Abilify to Physicians Treating Primarily Pediatric Populations.

1. <u>June 2005 through October 2007</u>.

137. Between 2005 and October 2007, Abilify's only FDA-approved indication was for acute manic and mixed episodes associated with Bipolar I Disorder, and Schizophrenia, in adults only. Between 2005 and October 2007, Abilify had

absolutely no FDA-approved indications for children or adolescents. Therefore, during this time, any promotion of Abilify for use in children or adolescents was necessarily off-label. During this time, BMS's RCC sales force focused on sales to facility-based providers, which for many representatives included those at children's residential treatment facilities and in the psychiatric departments of children's hospitals. Relator Edwards was an RCC sales representative for Abilify in Arizona and Las Vegas, and Relator Ibanez was an RCC sales representative for Abilify in Ohio.

138. Notwithstanding the plain dictates of government healthcare laws, Defendants directed their Abilify sales force to target pediatric physicians to illegally induce them to prescribe Abilify for children and adolescents.

139. For example, throughout the 2005-2007 time period, BMS directed the promotion of Abilify in child and adolescent psychiatric practices in the Cincinnati and Dayton, Ohio areas, including without limitation at the following locations:

a. Kettering Youth Services, Moraine, OH

b. St. Joseph Orphanage, Cincinnati, OH

c. Mercy Hospital Mt. Airy, Cincinnati, OH

d. Core Behavioral, Cincinnati, OH

e. Beechacres, Cincinnati, OH

f. South Community, Dayton, OH

g. MRDD facilities, Dayton and Huber Heights, OH

h. Cincinnati Children's Hospital Medical Center, Cincinnati, OH

i. CHILD FOCUS, Batavia, OH

j. Family Services, Covington, KY

k. NorthKey, all outpatient offices

l. NorthKey Inpatient hospital, Covington, KY

m. Neuroscience and Behavioral Association

n. Northern KY Psychiatry Associates

o. Talbert House, Cincinnati, OH

p. Day-Mont Behavioral Health Care, Inc., Dayton, OH

q. Samaritan Behavioral Health, Dayton, OH

r. Mental Health Recovery Center, Dayton, OH

s. ATS Behavioral, Dayton, OH

t. Eastway, Dayton, OH

u. Mahajan Therapeutics, Dayton, OH

v. Recovery Center Inc., Xenia, OH

w. Integrated Youth Services, Dayton, OH

x. Focus Care, Dayton, OH

y. Centerpoint Health, Cincinnati, OH

z. Wright-Patterson Air Force Base

aa. Practice of Vincent Ziegler. M.D.

bb. Practice of Tangvald and Associates

cc. Practice of Bruce Snider, M.D.

dd. Practice of Arnold Shapiro, M.D.

ee. Practice of Michael McIntosh, M.D.

ff. Practice of Gary Balster, M.D.

gg. Practice of Constance Ange, M.D.

hh. Practice of Sunita Agarwal, M.D.

ii. Practice of Christina Waite, M.D.

jj. Practice of Christina Weston, M.D.

kk. Practice of Stephanie Riolo, M.D.

ll. Practice of Robert Simms, M.D.

mm. Practice of Michael Maloney, M.D.

nn. Practice of Mary Matias Akhtar, M.D.

oo. Practice of Dr. Marlene Schmidt, M.D.

140. Further examples of Defendants' efforts to target pediatric physicians to illegally induce them to prescribe Abilify for children and adolescents include:

- Relator Ibanez's call targets between 2005 and 2007 included frequent calls upon and in-service training sessions provided to Wright-Patterson Air Force Base, including one such call on May 23, 2006. There, he called only on providers who saw child and adolescent patients in the hospital's child/adolescent inpatient unit, despite the fact that there were no approved pediatric indications for Abilify during this time.

- Relator Ibanez observed Otsuka representatives in his territory, Jeff Schneider and Alec Fisher, making inappropriate calls on child and adolescent providers. In addition to the inappropriate targets identified in BMS sales plans, Otsuka sales representatives called on a broad range of other inappropriate providers. Indeed, even in the infrequent case that a target was removed from the BMS database, that provider was often called on by an Otsuka representative.

- Relator Edwards was directed to call on the Melmed Center in Scottsdale, Arizona. The Melmed Center was founded and headed by Dr. Raun Melmed, a developmental and behavioral pediatrician and an international BMS speaker. The Center was originally called Developmental Pediatric Associates, and the majority of the patients at Melmed were pediatric patients. Like Relator Ibanez, Relator Edwards also worked with Otsuka counterparts, who marketed heavily to

> Melmed. During this time frame, Relator Edwards was told by her manager Scott Davis that she should leave samples of Abilify with the Melmed Center and that the two nurse practitioners who treated adult patients would sign for the samples to attempt to hide or disguise the off-label marketing activity. Mr. Davis told Relator Edwards that these samples would be utilized by the entire office of developmental pediatricians and not just physicians seeing adult patients.

141. Relator Edwards' BMS OBS retail sales representative counterparts were not restricted in call targets, and had free rein over their call lists. In yet another example of Defendants' efforts to target pediatric physicians to illegally induce them to prescribe Abilify for children and adolescents, in approximately January 2007, before Abilify had received any pediatric or children's indication, one of Ms. Edwards's OBS counterparts, Ron Rowden, gave a lunch presentation to physicians at Parc Place, an inpatient pediatric facility in Tempe, Arizona. Relator Edwards informed her manager Jeanne Flaherty of Mr. Rowden's inappropriate lunch presentation. Ms. Flaherty called Scott Davis, the OBS representative's manager. Relator Edwards is aware of no repercussions for Mr. Rowden as a result of his lunch presentation, and indeed, Mr. Rowden was promoted to the Oncology Division shortly thereafter.

142. Relator Edwards was also directed to call on Dr. Djavadi, a child/adolescent psychiatrist in the Rio Verde, Arizona area. Dr. Djavadi had a private practice, but he also served as a consulting psychiatrist for an adolescent inpatient unit at an area hospital, which had 80 beds for children with severe Bipolar Disorder.

143. In October 2007, BMS's RCC and ISS sales forces were dissolved and merged into the new Account-Based Sales (ABS) division. The Neuroscience division was thus divided into OBS, which continued to target office-based psychiatrists, and the newly formed ABS division. ABS continued to target Abilify sales to children's

residential treatments centers and now also targeted children's hospitals more broadly due to the dissolution of the ISS division, which had been responsible for targeting hospitals. Relator Edwards was assigned to OBS, and thus focused her sales on retail psychiatrists. Relator Ibanez was assigned to ABS. BMS representatives—both OBS and ABS—had counterparts at Otsuka who shared their territories and had overlapping targets. Otsuka representatives continued to call primarily on office-based providers, however, as before, they were not restricted to those settings and instead were instructed to sell to anyone willing to buy.

144. Also in October 2007, Abilify received its first pediatric indication—a limited indication for the treatment of Schizophrenia in adolescents aged 13-17. Not long thereafter, in February 2008, FDA approved an indication for Abilify for the treatment of manic and mixed episodes for Bipolar I Disorder for pediatric patients ages 10-17.

145. Even before Abilify obtained the new child/adolescent indications, and before BMS's reorganization, Defendants had been calling on pediatric psychiatrists to market Abilify.

146. Specifically, beginning in 2007, Relator Ibanez was the ABS representative in Dayton, Ohio and closely partnered with BMS representatives Jennifer Evans and Donald Conley, as well as Otsuka representative Jeff Schneider. In 2007, when Relator Ibanez was new to ABS sales, Ms. Evans introduced Mr. Ibanez to a number of ABS targets, including many pediatric targets including the mental health wing of Cincinnati Children's Hospital Medical Center. Ms. Evans was able to make those introductions because she and others on the OBS teams had been calling on

those pediatric targets since the launch of Abilify in 2002, notwithstanding that there was no pediatric indication until October 2007. Indeed, she made clear to Relator Ibanez that the pediatric psychiatry hospitals were market-share drivers for the OBS team.

147. In an effort to give the appearance of compliance with the CIA, shortly after Abilify received its first pediatric indication in October 2007 (and within days of BMS signing its CIA), Defendants processed their call lists using an algorithm designed to filter out pediatric physicians who treated children under the age of 13, the cutoff age for the new indication. The ABS sales representatives then received an "approved list" of child and adolescent psychiatrists, who were ostensibly treating primarily children over the age of 13, for promotion of Abilify.

148. The sales force was incensed because the revised list dropped a significant number of high-prescribing child psychiatrists, and the representatives knew this would negatively impact their sales metrics. But because Defendants had no intention of actually stopping their marketing efforts to those high-prescribers, physicians deemed inappropriate for inclusion on the call lists because they did not treat patients over the age of 13 could be added back easily with little or no oversight. Consequently, sales representatives added inappropriate providers back onto their lists, and BMS allowed them to do so. Specifically, in order to re-institute a physician on his or her call list, the sales representative provided the physician a survey delineating the age demographics of the target's practice and stating that the physician did not treat patients less than 13 years of age, which the physician was to fill out. Often, the physician was warned that if he answered in a way to indicate that he saw patients

under the age of 13, he would not receive samples, lunches, or calls in the future. Notably, these surveys were conducted only for selected physicians at the solicitation of the sales force. They were not comprehensively completed for all pediatric physicians nor was the information contained in them independently verified.

149. While BMS at least pretended to meet the mandates of the CIA by creating the appearance that it was reviewing its call lists, Otsuka didn't even try: Otsuka representatives continued to call on targets without regard to whether the physicians were re-identified on call lists or surveyed for appropriateness.

150. The uproar that followed when the new lists did not include a significant number of high-prescribing child and adolescent psychiatrists who had been on the previous lists is informative. Abilify had no child or adolescent indications prior to October 2007, and yet the sales forces' lists prior to October 2007 were populated with high-prescribing child and adolescent psychiatrists. Thus, it is clear that, prior to receiving any applicable indication, Defendants had been targeting pediatric physicians to illegally induce them to prescribe Abilify for children and adolescents, off-label, for noncovered, nonpayable uses.

151. After the initial post-adolescent-Schizophrenia BMS call list was issued, there was little additional effort to differentiate the targets for adult and pediatric indications, as required by the CIA. 2007 CIA, p. 10, Section III.B.3.f; 2008 CIA, p. 7, Section III.B.2.e. This is not surprising since, as Ms. Evans told Relator Ibanez, sales representatives got credit not just for every discharged patient on Abilify, but for any new prescriptions written by the same physician in his or her private practice. Because the sales representatives from both companies were compensated based on the

prescribing volume in their territories, this created significant pressure to call on a wide range of physicians, including inappropriate targets.

2. October 2007 to October 2009.

152. Despite the three limited child/adolescent indications they obtained for Abilify beginning in October 2007, Defendants continued to market Abilify to pediatric physicians for unapproved indications in children and adolescents.

153. From at least 2005 and continuing after Defendants began to obtain child/adolescent indications in October 2007, Defendants instructed their sales forces to reach patients with diagnoses beyond those for which Abilify was indicated by highlighting symptoms, rather than indications.

154. When selling to a children's home or to child psychiatrists, sales representatives touted Abilify's efficacy in treating agitation. They did so because they knew that those symptoms were common among children with Oppositional Defiant Disorder and Attention Deficit and Hyperactivity Disorder, two disorders seen with a much greater frequency in children than, *e.g.*, Schizophrenia, Bipolar I Disorder or irritability associated with Autistic Disorder.

155. In addition to marketing symptoms, Defendants explicitly marketed Abilify for off-label uses, including for use treating depression in children and adolescents. For example, in approximately February 2008, Ms. Evans scheduled a lunch at Kettering Youth Services, a children's psychiatric hospital, in order to introduce Mr. Ibanez as the new BMS representative for the hospital. Ms. Evans told Mr. Ibanez that BMS was successful in getting providers at the Kettering Youth Services to prescribe Abilify and that prescriptions generated by this account were vital to

Defendants' Dayton territory market share. Ms. Evans told Relator Ibanez that, as a result of BMS's efforts, Dr. Sunita Agarwal at Kettering Youth Services already routinely prescribed Abilify IM for agitated pediatric patients, and that he should work to maintain the "momentum" Abilify IM had at the pediatric hospital. Abilify IM is a fast-acting injectable form of Abilify that has only ever been indicated for use by adult patients with Schizophrenia or Bipolar mania. It has never been approved for use by children or adolescents.

156. Defendants' continued efforts to target pediatric physicians to illegally induce them to prescribe Abilify for unapproved indications in children and adolescents occurred in 2008 when Relator Ibanez received a request, from the Pediatric Intensive Care Unit (PICU) at Children's Hospital Dayton, for an "in-service" training session on the use of Abilify IM for pediatric patients in the ICU (and, specifically, to inquire about its use for chemical sedation). Relator Ibanez was concerned by the request since the use was off-label as Abilify IM was not approved for use in adolescents. Accordingly, Relator Ibanez contacted his District Manager Dion Smith for guidance. Mr. Smith approved the program and a lunch program was performed with paid BMS speaker, Dr. Jerome Schulte. Contrary to the program approved by Mr. Smith, BMS's CIA required it to use only Medical Science Liaisons, who theoretically were unaffiliated with BMS's sales functions, to respond to providers' requests for information regarding off-label uses. 2007 CIA, pp.29-30, Section III.L. BMS plainly was not permitted to deploy paid speakers to present on off-label uses.

157. Defendants also targeted pediatric physicians with marketing funds to illegally induce them to prescribe Abilify for unapproved indications in children and

adolescents. For example, Relator Edwards received a Direct Marketing Expense ("DME") Plan for Phoenix North 2008. For the first quarter of 2008, the instruction given by BMS was to "focus on Ped." It included five scheduled events for BMS speaker Dr. Roth, one of which occurred at the Melmed Center, the pediatric autism center in Scottsdale, Arizona. In the first quarter of 2008, Abilify did not have an approved indication for Autism in children or adolescents.

158. When the drug received its indication for MDD in adults, Defendants immediately began using this indication to persuade physicians to use Abilify to treat children and adolescents suffering from depression.

159. After this November 2007 approval, Relator Ibanez observed that a significant number of pediatric physicians treating patients under the age of 13 remained on call lists, and sales representatives who had only MDD promotional material for adults continued to promote Abilify to pediatric targets on their call lists. Abilify, however, has never been indicated to treat MDD in children or adolescents. On the contrary, the Black Box warning specifically warns that the use of Abilify to treat MDD and other psychiatric disorders in children, adolescents, and young adults leads to an increased risk of suicide and expressly states that “Abilify is not approved for use in pediatric patients with depression.”

160. In April 2009, Relator Edwards made a request to her manager Scott Davis that regional or national teleconferences be set up for child psychiatrists because she and the rest of the sales team lacked proper marketing materials for providers specializing in child psychiatric care. Though they were calling on child and adolescent providers, OBS sales people only had one visual aid to use, and it focused

on depression. Ms. Edwards summarized her request in an email update to her colleagues Denise Bueno, Anna Marie Mars, and Shauna Eginton, at Otsuka. Nothing happened in response to her concerns, and Defendants continued to call on child and adolescent providers despite having literature focused only on depression.

161. Relator Edwards's Field Coaching summary dated March 12, 2009 illustrates Defendants' emphasis on selling Abilify as a treatment for depression to inappropriate targets, including pediatric physicians, to illegally induce them to prescribe Abilify. On that day, she was observed and rated by her manager, Scott Davis. In a section regarding "Product Messaging Observations" she was to be rated based on how well she delivered particular product messages, but her actual rating was only related to MDD messaging. This was very typical of the directions she received in the Field Coaching Summaries—they emphasized MDD messages but never focused on, or provided any direction regarding, whether there was appropriately-tailored messaging for child psychiatric care. Relator Edwards's April 6, 2010 Field Coaching Summary also listed the same MDD messages.

162. As another example of Defendants' off-label promotion of Abilify for use in treating depression in children/adolescents, on October 29, 2009, BMS hosted a lunch at Pappadeaux's, in Phoenix, Arizona. Otsuka sales representative Shauna Eginton was also in attendance. During that lunch, Dr. John T. Hardy, a child and adolescent psychiatrist, one of the top Abilify prescribers, and a speaker frequently hired by Defendants, spoke on "MDD: Adjunctive Abilify for Adults Plus Review of Safety Data" to a group of providers. Drs. Ann Guthery and Edwin Perez, who both treat exclusively pediatric patients, attended.

163. One of the many ways Defendants manipulated the MDD indication was to persuade physicians, through the marketing of symptoms, to move Abilify up the "line of therapy," contrary to the limits of the indication. As a powerful antipsychotic indicated for adjunctive treatment for MDD, Abilify was typically prescribed at the end of the "line of therapy," meaning that Abilify would be prescribed if other methods, including SSRIs alone, increased dosages, and SNRIs, failed. But as a matter of business strategy, Defendants instructed their representatives to move the drug "up the line," rather than wait for a patient to fail multiple trials of monotherapy.

164. At a 2008 district sales meeting, Relator Ibanez's district business manager Dion Smith declared that if every physician augmented in the 3rd or 4th position, the company would go out of business, and he didn't want to see any physicians prescribing beyond the second augmentation position.[2] The physician who sparked this outburst was a child/adolescent psychiatrist, Dr. Sansone, who used Abilify as an adjunctive in the third or fourth position. This concept of using Abilify after multiple failed trials of monotherapy applies only to Abilify's MDD indication, where Abilify is indicated as an adjunctive—or augmenter—for the treatment of MDD, not as a stand-alone treatment for it. In contrast, Abilify is used as a stand-alone treatment for acute and manic episodes associated with Bipolar I Disorder,[3] Schizophrenia, and irritability related to Autism Disorder. Thus, it is clear that Dr. Sansone, a child/adolescent

---

[2] As alleged in paragraph 255, BMS also eliminated paid incentives, such as inclusion in the speakers' program, if physicians did not move Abilify "up the line."

[3] Abilify is also indicated as an adjunctive to lithium or valproate for patients in acute manic or mixed episodes of Bipolar I Disorder, but the same augmentation positioning does not apply.

psychiatrist, was being targeted by Defendants to increase his MDD usage, despite the lack of such indication for children.

3. Post-October 2009.

165. In direct contravention of the CIAs, which, *inter alia,* required Defendants to update their messaging and training in response to new indications, BMS did not reorganize its Neuroscience sales force to create a pediatric-focused division until two years after Abilify's first pediatric indication (for Schizophrenia, in October 2007), and one year after the second pediatric indication (for Bipolar I Disorder in February 2008). In October 2009, BMS re-organized the Neuroscience sales force into OBS and PFS. OBS representatives like Relator Edwards were directed to detail only the MDD message, while the now-PFS representatives like Relator Ibanez were directed to detail pediatric messages. And Otsuka never engaged in any such reorganization: throughout the relevant time period, Otsuka gave its sales force free rein to call on any provider, with any specialty, if the sales representative believed it would result in sales.

166. Unlike the period prior to this restructuring, OBS representatives were now trained only on MDD, and PFS representations were now trained only on pediatric materials. Likewise, OBS representatives were given promotional materials for the promotion of MDD only, and did not have any materials, or training, to detail the pediatric messages.

167. On November 17, 2009, Relator Edwards received a memorandum from her then-manager, Scott Davis. In the memorandum, Mr. Davis directed, "Sales message: 'MDD all the time…." This "MDD all the time" for OBS sales representatives

was a corporately-directed message delivered to all Abilify sales representatives. For example, a March 17, 2010 memorandum to the national sales force made clear that "OBS (Office-Based Specialists) will deliver Adult Adjunctive MDD calls to their targets." The national memorandum directed that OBS reps were not to plan pediatric promotional programs "based on the business decision to focus on Adult Adjunctive MDD as the #1 opportunity."

168. Notwithstanding this message, child and adolescent providers remained on the call lists of OBS sales representatives. Because sales representatives were required to call on all targets on their call lists in order to meet their quotas, Relator Edwards was increasingly pressured by BMS management to call on child and adolescent provider targets. She became very concerned with the continued assignment of these targets, and the inappropriate promotion necessitated by these assignments. She was instructed to promote "MDD-only," an indication that Abilify never approved for children; Abilify carried a Black Box warning with respect to children suffering from MDD; and she was not provided with any materials or training to detail an appropriate pediatric message.

169. Relator Edwards's call plan for the 3rd and 4th Quarters of 2009 included a directive to put resources and time toward a specific group of physician targets (samples, DMEs, coupons—office contact at least once a week). Five of the six offices to which Relator was assigned were child psychiatrists: Chundu, Tan-Fermo, Djavadi, Perez and Prince. Her counterparts at Otsuka, Shauna Eginton and Anna Marie Mars, were also assigned child psychiatrists. Ms. Eginton had seven child

psychiatrists on her call list and Ms. Mars had five. The call plan directed BMS and Otsuka reps to make calls at least once a week on each target.

170. The directive to inappropriately target child and adolescent providers was driven home by the demand that representatives call on "high quintile" providers, most of whom were child and adolescent providers. "High quintile" refers to high atypical antipsychotic prescribers. All physicians were divided into quintiles based on the number of prescriptions they wrote for atypical antipsychotics, with Quintile 5 being the highest ranking.

171. In 2008 and 2010, BMS manager Scott Davis instructed OBS sales representatives to "[f]ocus on getting 60% Quintile 5 & 4 and 40% of Quintiles 3, 2, &1 to DME Program" and that planning was "critical." The ability to hit these assigned goals affected bonuses, annual base salary, and reviews, and in turn affected whether the representatives would stay employed.

172. Most of the Q5 and Q4 providers were pediatric prescribers. For example, a Physician Level Report received by Ms. Edwards in November 2009 indicated that approximately 15 of the 33 Q5s and Q4s are child or adolescent providers.

173. Because there were not enough adult-only high-quintile providers for OBS representatives to meet their assigned quotas or the SAS/CAS, or justify 60 percent of the lunch and DME budget, OBS representatives were instructed to continue to call on child and adolescent providers. Without pediatric training or materials, OBS representatives were required to detail inappropriate MDD messaging to child and adolescent providers.

174. After October 2009, Relator Ibanez similarly observed that OBS counterparts in Ohio were calling on "high quintile," child and adolescent providers and delivering an improper MDD message.

175. In November 2009, at the breakout sessions for her district at the regional meeting in La Jolla, Relator Edwards voiced her concerns regarding the inappropriate targets on her list and her concerns with giving MDD-only presentations to child and adolescent providers. Additionally, she expressed her concerns about the compliance issues relating to how sales representatives were directed to conduct inappropriate calls. In discussions on this issue that ensued in November and December, she was assured by BMS that the lists would be "cleaned up," *i.e.* child and pediatric prescribers would be removed from the call lists of OBS sales representatives.

176. Relator Ibanez expressed similar concerns to BMS regarding his OBS counterparts calling on PFS targets: In a December 28, 2009 email to the BMS compliance helpline, Mr. Ibanez identified questions he had regarding the widespread practice of BMS and Otsuka OBS representatives calling on PFS targets. He specifically raised questions regarding the appropriate roles of OBS and PFS representatives. He reported that: "[t]he issue being faced in all areas of the country is that BMS and Otsuka OBS are still calling on PED-ONLY Psychiatrist[s]," even though they were required to make MDD-only presentations to all providers.

177. In addition, in his district breakout with the District Manager at the January 2010 National Sales Meeting in Dallas, at which both BMS and Otsuka were present, Relator Ibanez presented a Power Point on the "Opportunities" and "Challenges" for PFS in his Cincinnati territory (a typical update given by all the

representatives at that meeting), and specifically identified that a challenge was "OBS Calling PFS Targets." His presentation posed the question: "Need to Define --What is an OBS target? --What is [a PFS] Target? Compliance or Non-Compliance." His questions were not addressed by BMS.

178. Despite these concerns raised by Relators, and the clear mandates of the CIAs, BMS's attempts to purge inappropriate providers from call lists were deliberately ineffective. BMS sales representatives were directed to review their call lists in the Call Max system to conform their call lists to those targets relevant to their respective message. For OBS, that meant targets suitable for the MDD-only message, which was the corporate directive issued at that time, and for PFS, that meant targets suitable for the limited child and adolescent Bipolar, Schizophrenia, and Autism-related irritability messages.

179. The deadline for sales representatives to clean up the lists was November 7, 2009, and then a second "snap-shot" was to be taken on December 31, 2009. After the changes were entered into the system, the data was to be switched to a new system, Navigator. The Navigator system was to be introduced at the National Sales Meeting in Dallas in January 2010, and all Abilify sales representatives, including Otsuka representatives, were to use Navigator after that meeting.

180. The "clean-up" was performed exclusively by the sales representatives, and Defendants did not obtain objective, verifiable data regarding physicians' actual patient populations, surveys, or other objective measures. Instead, they relied solely on the veracity of the sales representatives, who had a vested interest in maintaining high-prescribing, if inappropriate, physicians on their lists.

181. Unlike call-list reviews that had occurred prior to the effective date of the CIA, no comprehensive, meaningful surveys were conducted in conjunction with the call lists developed to promote the adult and narrow pediatric indications obtained in 2007 and 2008, or in conjunction with this supposed 2009 effort to remove inappropriate targets from the lists. Defendants' decision to not seek objective, verifiable data regarding physicians' actual patient populations, surveys, or otherwise, underscores the fact that Defendants never truly intended to ensure that their sales forces were operating within the bounds of the CIA, and within the bounds of the law.

182. Defendants' call list clean-up efforts were problematic for at least three reasons: (1) the sales teams were incentivized by their compensation plans not to remove targets; (2) when Relator Edwards and many other representatives submitted recommended changes to their call lists within the deadlines provided, Defendants' management ignored those recommendations; and (3) even had Defendants' subjective 2009 "clean up" been implemented, the changes to the call lists would have come two years after the new indications, and thus would have wholly failed to meet Defendants' obligations under the CIAs. 2007 CIA, p. 10, Section III.B.3.f; 2008 CIA, p. 7, Section III.B.2.e.

183. The failure to review the call lists and remove inappropriate targets resulted in the continued off-label promotion of Abilify by BMS and Otsuka sales representatives.

184. OBS sales representatives, armed with only their MDD training and materials, routinely called on the child and adolescent providers that Defendants refused to remove from their call lists. For instance, on March 10, 2010, Scott Davis

presented his 2010 District plan to Johanna Mercier, the head of Sales. Titled "#1 Key Opportunity/Initiatives – Selling Like an Antibiotic Rep," Davis's presentation outlines opportunities and initiatives for PFS and Child/Adolescent Indications. This document reflects that there were 86 PFS-only psychiatrists in Arizona and that these physicians required weekly calls, but there were only two PFS representatives in the Phoenix, Arizona Neuroscience division of BMS. It was not feasible for only two PFS representatives to make weekly calls on all of these physicians and, in fact, Relator Edwards is aware that Jack Briggs, one of the two Phoenix, Arizona PFS representatives, was assigned a call list comprised of only a few of the PFS-only physicians. Many of the physicians on his list appeared on the OBS call lists, and were shared targets. Since these same shared targets were treating primarily children and adolescent populations, it was inappropriate for them to be called on by OBS sales representatives, with their MDD-only presentations.

185. Davis's district plan also directed representatives to utilize only "high value" speakers, meaning those in high quintiles, who write the most prescriptions for Abilify, and who had a solid reputation, such as Drs. Rabin, Hardy, Fleming, Escolona. Davis's district plan further directed representatives to "communicate with Otsuka Reps on these specific targets (Q5, Q4, & Q3) weekly with specific actions."

186. In April 2010, BMS sales representatives, including Relators, received a voicemail blast from BMS Regional Business Director Steve Mahle stating that BMS was going to remove 1300 physicians from the OBS lists. The April 2010 call lists were issued with most of the names from the prior lists still on them, in direct contravention of the CIA. 2007 CIA, p. 10, Section III.B.3.f; 2008 CIA, p. 7, Section

III.B.2.e. For example, in April 2010, Otsuka OBS representative Alec Fisher had the following high quintile child and adolescent providers on his "bucket list": Drs. Joseph Cresci, James Eppley, Michael McIntosh, Wayne Harrison, Hugh Pettigrew, Rodney Vivian, Arnold Shapiro. As an OBS sales representative, Mr. Fischer could only promote Abilify for MDD, making any attempt by Mr. Fisher to market Abilify to these physicians illegal off-label promotion.

187. To demonstrate the sham nature of the call-list reviews (which occurred many years after the CIAs), the following pediatric-focused physicians in Arizona are examples of pediatric targets identified on OBS call lists in 2009, and not removed as part of any prior review:

	Name	**Quintile**
1	Letty Tan-Fermo	Q5
2	Leticia Jacinto	Q5
3	Derrick Hines	Q4
4	Leslie Kaminski	Q4
5	Benet Press	Q4
6	Nicholas Farrey	Q2
7	Judith Outten	Q4
8	Houshang Semino	Q4
9	Timothy Miller	Q4
10	Ann Guthery	Q4
11	Mary Nowlin	Q3
12	Elias Ruioba	Q3
13	Mark Harp	Q3
14	Sharon Paul	Q2
15	Vidnod Patel	Q5
16	Edwin Perez Vega	Q4

188. The following physicians in Ohio are examples of pediatric targets identified on OBS call lists in 2009, and not removed as part of any prior review:

	Name	Quintile
1	George Broderick	Q2
2	Elizabeth Cottingham	Q3
3	Joseph Cresci	Q5
4	Melissa Delbello	Q2
5	Sergio Delgado	Q2
6	Carol Engel	Q3
7	James Eppley	Q5
8	David Franz	Q3
9	Elliott Friedeman	Q5
11	Richard Honig	Q2
12	Jennifer Johnson	Q3
13	Mark Johnson	
14	Marcia Kaplan	Q3
15	Velissarius Karacostas	Q2
16	Monica Kennedy	Q3
17	Robert Kowatch	Q3
18	Michael McIntosh	Q4
19	Sarah Morrison	Q2
20	Jayasree Nandagopal	Q2
21	Daniel Nelson	Q3
22	Erik Nelson	Q2
23	Jayanthi Peters	Q2
24	Hugh Pettigrew	Q4
25	Erik Powell	
26	Marlene Schmidt	Q3
27	Roslyn Seligman	
28	Arnold Shapiro	Q3
29	Janice Singerman	Q2
30	Robert Sorscher	Q3
31	Michael Sorter	Q3
32	Jeffrey Strawn	
33	Daniel Vogel	Q3
34	Sharon Wynn	Q2

189. The following physicians in Arizona are examples of pediatric targets still identified on OBS call lists in 2010, and not removed as part of any prior review:

	Name	Quintile
1	Leslie Kaminski	Q4

2	Benet Press	Q4
3	Nicholas Farrey	Q2
4	Houshang Semino	Q4
5	Mary Nowlin	Q3
6	Elias Ruioba	Q3
7	Mark Harp	Q3
8	Sharon Paul	Q2

190. The following physicians in Ohio are examples of pediatric targets still identified on OBS call lists in 2010, and not removed as part of any prior review:

	Name	Quintile
1	George Broderick	Q2
2	Elizabeth Cottingham	Q3
3	Joseph Cresci	Q5
4	Melissa Delbello	Q2
5	Sergio Delgado	Q2
6	Carol Engel	Q3
7	James Eppley	Q5
8	David Franz	Q3
9	Elliott Friedeman	Q5
10	Larry Graham	
11	Richard Honig	Q2
12	Jennifer Johnson	Q3
13	Mark Johnson	
14	Marcia Kaplan	Q3
15	Velissarius Karacostas	Q2
16	Monica Kennedy	Q3
17	Robert Kowatch	Q3
18	Michael Maloney	
19	Michael McIntosh	Q4
20	Sarah Morrison	Q2
21	Jayasree Nandagopal	Q2
22	Daniel Nelson	Q3
23	Erik Nelson	Q2
24	Jayanthi Peters	Q2
25	Hugh Pettigrew	Q4
26	Erik Powell	
27	Marlene Schmidt	Q3
28	Roslyn Seligman	
29	Arnold Shapiro	Q3
30	Janice Singerman	Q2
31	Wiley Smith	

32	Sorscher, Robert	Q3
33	Sorter, Michael	Q3
34	Jeffrey Strawn	
35	Vogel, Daniel	Q3
36	Wynn, Sharon	Q2

191. The call notes reflect that these physicians were easily identified as child and adolescent providers by the sales team, but were not removed from the OBS call lists on multiple occasions over time. For example, on April 15, 2008, call notes reflect a sales representative calling on Dr. Jayasree Nandagopal and noting, "MDD indication/primarily dealing with child pop so applicability limited – not very responsive person – get to know better…" The call note for Dr. Nandagopal on 4/19/08, states that "Patient pop (population) almost exclusively adol[escent]…" yet despite these observations, Dr. Nandagopal continued to appear on the OBS call lists through 2010.

192. In early April 2010, Relator Ibanez observed a lunch "in-service" presentation by an OBS representative. The representative discussed adult depression with the physician, Sharon Wynn. When Dr. Wynn told the representative that she does not see adult patients, he said "that's ok; I am talking about patients with depression, not adults in general."

193. Relator Edwards observed that BMS routinely invited child and adolescent physicians to lunches, dinners, and other speaker programs promoting the use of Abilify for depression. By way of example, an MDD speaker program took place at a dinner meeting for the Arizona Child Psychiatry Association in 2008 with approximately 25-30 child psychiatrists in attendance. Indeed, beginning with the November 2007 receipt of the MDD indication and continuing thereafter, Defendants undertook a national campaign of "city-wide" dinner meetings focused on MDD

promotion. Such meetings were held at high-end venues, such as the restaurant at the Sanctuary Camelback Mountain Resort and Spa in Scottsdale, Arizona, and every one of them was attended by child/adolescent psychiatrists.

194. On or around April 13, 2010, Relator Ibanez was invited to a meeting with BMS District Manager Keith Watters, BMS OBS representative Marty Hensley, and Otsuka representatives Alec Fisher and Cary Harris. In the course of the meeting, Mr. Watters asked each representative to identify and discuss their top prescribers. Dr. Joseph Cresci, child and adolescent psychiatrist, was identified by both Mr. Hensley and Mr. Fisher as their top prescriber for Abilify. Dr. Cresci worked at Beech Acres Parenting Center, in Cincinnati, Ohio, a pediatric care organization. He did not treat adults. Mr. Hensley and Mr. Fisher went on to say that Cresci's Abilify numbers were dropping and that they needed to regain his trust. Mr. Harris then reported that he was working on a free trip for Dr. Cresci to the Kentucky Horse Park. As OBS sales representatives, Mr. Hensley and Mr. Fischer were armed with only their MDD training and materials. Thus, any sales calls they made to Dr. Cresci necessarily entailed off-label marketing.

195. Also at that meeting, Dr. Elliott Friedeman was described as writing "declining" Abilify prescriptions. Mr. Hensley told the meeting members that he spoke with Dr. Friedeman about picking his favorite restaurant in order to entertain the physician, and that he was considering the creation of a speaker program to offer to Dr. Friedeman. As an OBS sales representative, Mr. Hensley was armed with only his MDD training and materials. Thus, any promotional efforts he made to Dr. Friedeman would necessarily entail off-label marketing.

196. Mr. Hensley stated to Relator Ibanez that "the message and type of doctor is not important." Rather, "it is about selling Abilify no matter what!" Mr. Hensley also stated that a physician who sees at least one adult patient is sufficient to make that physician a valid target. Mr. Watters also added: "Don't you want OBS helping you in your accounts?" Mr. Watters made clear that "depression sales will make [BMS] number one;" and that "doctors who augment will be targeted regardless of specialty."

197. In late 2011 and early 2012, BMS district managers had sales call planning sessions (called "AIMS/BET" sessions) with their respective district direct reports. These were required sales message planning sessions where the manager reviewed the assigned sales message for each targeted physician, using the call lists and plans that had been created and assigned by Defendants. Any adjustments in the message suggested by the representative had to be approved both by the manager and the regional office. BMS sales representative Albert "Al" Zennie told BMS PFS sales representative Sally Maynard that, during his planning session with District Manager Keith Watters, the company had assigned off-label MDD calls on child/adolescent psychiatrists. Mr. Watters and Mr. Zennie changed the calls to child-approved indications and submitted a final call list for Regional Office Approval. The changes were denied by Regional Manager Michelle Calope, who insisted that Mr. Zennie provide an MDD-only message.

198. The same thing happened to Ms. Maynard and her call list when she suggested changes to the list that would bring the list and the message into compliance. In direct contravention of the dictates of the CIA, 2007 CIA, p. 10, Section III.B.3.f; 2008 CIA, p. 7, Section III.B.2.e., and with blatant disregard for the law, Ms.

Calope denied the changes recommended by Ms. Maynard and her manager, Steve Rosi. Ms. Calope changed the plan back to the original MDD-only message which she insisted Ms. Maynard give. Ms. Calope stated to her region that no changes will be approved and they must adhere to the company-directed messaging. As Ms. Maynard put it, the message was, "If the company says MDD, that means MDD calls. Physician specialty will not be an excuse!" Ms. Calope also stated that the company uses ICD-9 diagnosis codes to determine what type of message the physician should receive. Hence, if a psychiatrist treats a high amount of depression patients, then they were to receive a depression call without regard to whether they treat adult or child patients. Ms. Calope also reinforced that each sales representative was to maintain an 80% score on adherence to the call plan.

199. At the same time that Defendants' OBS representatives, trained only on MDD messages and inappropriately delivering those messages to pediatric providers, PFS representatives continued to promote Abilify for uses beyond its limited approved indications.

200. Further, OBS and PFS representatives alike continued to misrepresent the safety, efficacy, and uses for Abilify in children. For example, Abilify sales representatives were instructed not to discuss the long-term side effects and focus only on short-term effects, when asked. The registration trial for the Bipolar I Disorder pediatric indication was four weeks, and no significant weight gain was seen during that short duration. However, subsequent studies that were conducted for longer periods of time showed a risk of weight gain. Relator Ibanez was trained to describe Abilify as weight-neutral., notwithstanding that published, long-term data. At a PFS

breakout session during a national meeting in 2010, BMS corporate management instructed PFS sales representatives, including Ibanez, not to discuss with providers the long-term data showing that Abilify caused weight gain and instead to say that there were no clinically significant weight gain issues in Abilify trials.

201. Additionally, Defendants marketed Abilify as a safer alternative to its main competitors, Seroquel and Risperdal, notwithstanding the lack of FDA-approved studies to support those assertions. Any statement or implication that Abilify had a superior safety or efficacy rate compared to other antipsychotic medications were false and misleading absent adequate, well-controlled, FDA-approved comparative studies.

C. Illegal Off-Label Promotion of Abilify to Physicians Who Treat Primarily Elderly Patients.

202. Between June 2005 and October 2007, Defendants' sales representatives were also inappropriately marketing Abilify to providers whose patient populations included a high number of patients suffering from dementia. During that time frame, Abilify was indicated only for Schizophrenia, and manic and mixed episodes associated with Bipolar I Disorder. Notwithstanding the small percentage of patients with Schizophrenia and Bipolar I Disorder in nursing homes, Abilify sales representatives were directed to sell the symptoms of Schizophrenia and Bipolar I Disorder, symptoms that are frequently exhibited by patients with dementia.

203. Because patients with Schizophrenia and Bipolar I Disorder represent such a small fraction of the patients institutionalized in nursing homes, marketing Abilify in nursing homes is like marketing to a "ghost population." The particular danger of marketing to a ghost population among the elderly in institutions is

that the very real population of elderly patients with dementia comprises the majority of patients targeted by such marketing. Indeed, Defendants were well-aware of the fact that they were marketing to a ghost population and chose to ignore the associated dangers: in its training for RCC sales representatives, BMS noted that only 3% of the patients in long-term-care facilities have Schizophrenia and somewhere between 50-70% of patients in nursing homes suffer from dementia. In fact, RCC representatives were trained that long-term-care facilities were the most important type of facility for them to target, noting that the reason to prescribe Abilify in such an environment was because of the patients with dementia presenting with psychosis and resulting behavior problems. Of course, as Defendants knew well, the FDA expressly and dramatically warned against the use of Abilify by people with dementia.

204. Conveniently for Defendants, many of the symptoms of indications for which Abilify was approved are present in patients with dementia, and Defendants knowingly exploited that fact. By marketing Abilify to treat symptoms that may exist in the elderly, Defendants intended to induce the prescribing of Abilify off-label to elderly patients with dementia. When Relator Edwards was an RCC representative, she routinely presented in-service trainings to long-term-care facilities, in which she painted the following picture, consonant with BMS directives, “Which of these do you see in your facility? Kicking, biting, screaming, hostility, suspiciousness, delusions (Mom’s not really there!), grandiosity (Son of Christ? End is near!), visual or auditory hallucinations? Can anyone think of a criminal with such hallucinations? Son of Sam. He was killing people because his dog was telling him to do so.” She would go on to say, “By helping with these you help restore some quality of life. Seeing someone slumped over in the bed,

drooling in the corner with no response is really disheartening for everyone. Abilify will awaken them." This type of "quality of life" marketing is false and misleading because Defendants had no adequate or well-controlled studies to determine any health-related quality of life benefits.

205. In April 2005, FDA issued a Public Health Advisory warning that increased mortality was associated with the use of Abilify in elderly patients with dementia. In February 2006, FDA required the inclusion of a Black Box warning on the label, advising that Abilify had been associated with "INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS." By marketing Abilify to treat the symptoms generally experienced by elderly patients in nursing home settings, Defendants intended that physicians disregard the Black Box warnings, and serious dangers of Abilify, and prescribe Abilify for patients suffering from dementia.

206. Notwithstanding these clear safety warnings, when Relator Ibanez was assigned to the RCC division, he was directed to market Abilify to the Alois Alzheimer Center, a facility located in Cincinnati, Ohio, treating patients with Alzheimer's disease and dementia. He questioned his district business manager at that time, Ellen Weaver-Bailey, regarding the implications of marketing off-label by presenting Abilify in that facility, and specifically raised his concerns about the Black Box warning regarding dementia patients. Ms. Weaver-Bailey directed Relator Ibanez to proceed and to have Dr. Bill Kasper, a Doctor of Pharmacy and BMS Medical Science Liaison, perform the "in-service" training session. Based on that instruction, Relator Ibanez organized a catered lunch for the Alois staff. Dr. Kasper presented the Abilify Schizophrenia & Bipolar I Disorder speaker's slide deck, and received numerous questions regarding the

similarity of symptoms between dementia and Schizophrenia and Bipolar I Disorder. Consistent with the BMS corporate message, Dr. Kasper discussed with the staff that the efficacy of symptom control in the BMS studies would indeed help the center control their dementia patients with similar symptoms. At no time during the presentation did Dr. Kasper mention Abilify's Black Box warning for dementia patients.

207. As Relator Ibanez's supervisor during his time in RCC, Ellen Weaver-Bailey explicitly instructed her staff to never use "the D word" when selling to long-term care facilities but, instead, to "sell the symptoms" of dementia.

208. During his time both with RCC and ABS, Relator Ibanez was instructed by his supervisors to acquire the account lists from the regional long-term-care pharmacies that provided drugs to the area nursing homes. Those lists contained not only the names of the nursing and other long-term-care facilities, but also the names of their medical directors and other key personnel. That information was particularly valuable to Defendants because those were the people who could influence the volume of Abilify sales and were the critical driver for the long-term-care pharmacy business. The information was also valuable for the sales representatives because they got credit for all Abilify provided by the long-term-care pharmacies to the facilities in their region. Once he got a copy of those account lists, *e.g.*, from a friend at an Omnicare pharmacy, Relator Ibanez provided them to his district and regional manager, and the information went up the corporate chain. The names identified on those lists was then incorporated into the RCC and, later, ABS call lists.

209. One such list of Omnicare's regional long-term care, skilled nursing, group home, and other accounts contained 42 facilities with an aggregate of

5,218 beds, and, as directed, Relator Ibanez provided it to his supervisors, who shared it up the line. The key market-driver prescribers included in that list were then incorporated into Relator Ibanez's call lists.

210. After November 2007, when FDA approved Abilify for use as adjunctive therapy for the treatment of MDD in adults, Defendants aggressively targeted elderly nursing-home patients suffering from dementia. They did so by promoting Abilify's efficacy in treating depression-like symptoms, which are common in that population. Sales representatives were instructed to sell the symptoms of MDD to physicians providing care to geriatric patients, even though there was no data to support the safety, efficacy, or tolerability of Abilify in their patients. Further, Defendants' sales representatives were never instructed to disclose, in their conversations with the prescribing physicians, the fact that Abilify carried a Black Box warning for dementia patients.

211. During a 2008 regional sales strategy meeting in Columbus, Ohio, Relator Ibanez was involved in an ABS Breakout training session regarding "selling in the Nursing Home Environment." Terry McCurren, then-current BMS district business manager, led the session. He told the ABS team that it is not illegal to discuss or promote Abilify for the treatment of dementia if the physician asks an unsolicited question. Mr. McCurren also told the team that they should sell Abilify as "not contraindicated for dementia," intending to communicate that it was safe and effective to prescribe Abilify for patients suffering from dementia. This message misrepresents the safety of Abilify for use by patients with dementia, and flatly contradicts the FDA-mandated Black Box warning noting increased mortality risks in such patients.

212. Further, Mr. McCurren's instructions contravene the provisions in BMS's CIA governing protocol for responding to providers' questions concerning off-label uses of Abilify. Under BMS's CIA, sales representatives were required to respond to such questions by submitting written information request forms to BMS, which would deploy employees unaffiliated with the sales department to address the providers' questions. 2007 CIA, pp.29-30, Section III.L.

213. Like Mr. McCurren, district business manager Dion Smith instructed Relator Ibanez throughout 2008-09 to sell Abilify by stating it was "not contraindicated for dementia," citing positive trials with patients suffering from dementia. Directly contrary to this message, the FDA-approved labels for Abilify at the time expressly warned that Abilify was "no approved for the treatment of patients with dementia-related psychosis." Indeed, the 2009 Abilify label describes the dementia-related clinical trials of the drug including a trial that found treatment-emergent adverse effects including lethargy, sedation, incontinence, and excessive salivation at a rate at least twice that of placebo. As with the drug's original 2002 label, the 2009 label then states, "The safety and efficacy of ABILIFY in the treatment of patients with psychosis associated with dementia have not been established."

214. In 2008 and 2009, the ABS sales force was encouraged to use the sales aid, "Adjunctive Use of Abilify for MDD," in nursing homes. The ABS sales force also used a sales aid, "Nursing Home Core Visual Age," the aid Dr. Richtand objected to using, which showed a picture of a 63-year-old nursing home patient named "Mary" with the prominent statement that "more than one third of nursing home residents have a diagnosis of MDD." The front page of the sales aid prominently lists some symptoms

of depression: "Depressed mood, Loss of energy, Loss of interest, Feelings of worthlessness, Sleeping too much."

215. ABS representatives were instructed to "paint the picture" of 63-year-old "Mary" residing in a nursing home, notwithstanding the fact that nursing homes are rarely populated by 63-year olds at all, let alone those with MDD but without dementia. They were trained to identify one symptom of depression touted in the visual aid, all of which happen to be common symptoms among those with early onset dementia.

216. The sales force was directed to lead promotional calls with symptoms and treatment of symptoms, instead of diagnoses. They focused heavily on cognitive difficulties, aggressiveness, lethargy, and irritability, all symptoms that could be tied to the approved indications for the drug but which are also present in many people who don't have Schizophrenia, Bipolar I Disorder, or MDD. The data in the BMS materials addressed:

Apparent Sadness	Concentration Difficulties
Reported Sadness	Lassitude
Inner Tension	Inability to feel
Reduced Sleep	Pessimistic Thoughts
Reduced Appetite	Suicidal Thoughts

217. For example, a May 2008 ABS Teleconference directed the Abilify sales team to market to "state institutions" for "patient types identified with MDD" by focusing on the symptom presentation of "concentration difficulties," "pessimistic thoughts" and "suicidal thoughts," citing that "[u]sually Geriatric population on multiple medication, 20 years or more in the facility."

218. In an "Assisted Facility Guide," the Abilify sales force was directed to "concentrate on how to identify the [symptoms] of depression."

219. In a training in 2009, Relator Edwards was instructed by BMS to "close" her sales pitch with the following: "If I can show you that Abilify can help with (symptoms), on top of that, the FDA has given the approval for it, will you try Abilify for the (symptoms) patient?"

220. Relator Ibanez was encouraged by his manager to obtain prescriptions of Abilify for "lethargic" nursing home patients. Relator Ibanez, like other sales representatives, would provide pre-call planning notes to their managers regarding calls to long-term care physicians. Relator Ibanez's notes often reflect the goal, as directed by his manager, of obtaining prescriptions of Abilify for "lethargic" nursing home patients. Similarly, in one set of notes, from July 2009, Mr. Zennie documented a call with Dr. Scheidler that indicated he would agree to prescribe low-dose Abilify for lethargic patients. Also, call notes for Dr. Hernandez at the Lodge Care Center in January 2009 reflect he was "committed to prescribe for lethargic patient." Through these marketing efforts, Defendants intended that physicians prescribe Abilify for patients suffering from dementia.

221. BMS also instructed its sales force to sell Abilify to nursing-and-residential home providers by telling them that if they put patients on Abilify, they would receive fewer calls in the middle of the night from staff complaining about unruly, uncooperative, and agitated patients. Indeed, Defendants routinely sold Abilify by asking the providers if they saw patients with memory impairment or aggression

towards others, both of which are symptoms of dementia and commonly seen among the institutionalized elderly.

222. By way of further example of Defendants selling Abilify as a way to calm agitated and disruptive elderly patients with dementia, BMS engaged in a targeted push to get Abilify IM added to the emergency psychiatric kits that nursing homes and other long-term-care facilities have on site. These kits include injectable medication designed to mollify the unruly, violent elderly patient. BMS instructed its sales force to sell Abilify to the pharmacies that supplied these kits, like Omnicare, by marketing the drug as a way to control the patient without the side effects of Haldol and Ativan. The representatives would say, for example, "You just want to get the patient to stop biting and kicking—you don't want the patient's kids to see Mom or Dad sitting in a chair drooling."

223. In the geriatric psychiatric units in hospitals, the pitch was similar: there, Defendants would sell Abilify as a way to deal with the combative patient by using Abilify IM as a booster. The sales representatives would say, for example, "you're an acute-care facility—you want to get these patients stabilized and out the door. Putting them on Ativan will drag that process out because it will knock them out for days. If you prescribe oral Abilify right away and give an IM shot as a booster, you'll turn beds quicker."

224. Defendants' marketing of Abilify as a way to control hostile elderly patients is deliberately misleading, as it implies without any substantiation that Abilify was specifically shown in clinical trials to be effective in treating the symptom of hostility in elderly patients.

225. Relator Ibanez called on a range of nursing home medical directors and consultant psychiatrists throughout 2008 and 2009, including Drs. Hernandez (an internal medicine physician who served as medical director of several nursing homes in the Greater Cincinnati area, including, *e.g.*, The Lodge), McConnell (a family medicine physician who served as medical director of various nursing homes in Vandalia, Ohio), Scheidler (an internal medicine physician who had a private practice but also served as medical director of at least one nursing home, Chesterwood, in West Chester, Ohio), and Shackson (a consulting geriatric psychiatrist for many nursing homes in Cincinnati).

226. Relator Ibanez was required to submit information regarding his contacts with the physicians to his district business manager, Dion Smith. Relator Ibanez would report notes of the physician's concern and his planned focus for the following visit. Mr. Smith used this information to prepare for when he would join his sales representatives on calls. By way of example, the call notes for Dr. Hernandez on May 27, 2008 reflected "scheduled MDD inservice Glendale Place Care Center;" on June 18, 2008 stated "having great success with A for MDD patients in LTC;" and on January 16, 2009 "now rxing for MDD Nursing Homes."

227. During some promotional sessions, some physicians expressed their objections to the use of the atypical antipsychotic Abilify for their patients because generally their patients are demented, and not depressed. For example, in late 2009, Dr. Neil Richtand, of the University of Cincinnati Department of Psychiatry, was asked to present the BMS slide deck for a BMS speaking engagement entitled "Patients in Nursing Homes with MDD," and the sales aid "Nursing Home Core Visual Age." He refused, stating that the use of an atypical antipsychotic in the geriatric population is not

valid, safe or ethical, and that there was no current data to support the use of Abilify or other similar agents in elderly patients. Dr. Richtand specifically questioned that Abilify was being promoted to address behavior and symptoms, and not disease.

D. Defendants' Illegal Promotional Schemes Included False and Misleading Statements and Omissions.

228. As instructed by Defendants, Defendants' sales forces delivered a wide range of false and misleading messages to induce providers to write prescriptions of Abilify for off-label uses.

229. Before 2007, Defendants' sales representatives marketed Abilify to a legion of children's providers before Abilify was approved for *any* indications in children. Once Abilify was approved for limited uses in children, Defendants continued to market it illegally, promoting it for uses beyond the limited approved use.

230. For example, even after Abilify was indicated for limited uses in children, sales representatives marketed it for MDD in children. These representatives, some trained only in using Abilify as a treatment for MDD in adults and equipped only with corresponding promotional materials, were directed to sell Abilify for MDD, multiple times each quarter to child/adolescent providers, despite the drug not having an indication for such use in adolescents and despite there being no safety or efficacy studies of the impact the drug would have on a depressed adolescent.

231. Among the many specific examples of Defendants' improper promotion of Abilify for MDD in children, Relator Edwards's call plan for the 3rd and 4th quarters of 2009 included a directive to put resources and time toward the following child psychiatrists, even though she had only MDD materials: Chundu, Tan-Fermo, Djavadi, Perez and Prince. Her counterparts at Otsuka, Shauna Eginton and Anna

Marie Mars, were also assigned child psychiatrists. At the time, Edwards and her Otsuka counterparts had only MDD materials.

232. Similarly, as of April 2010, Otsuka OBS representative Alec Fisher still had the following high quintile child and adolescent providers on his "bucket list": Drs. Joseph Cresci, James Eppley, Michael McIntosh, Wayne Harrison, Hugh Pettigrew, Rodney Vivian, Arnold Shapiro. As an OBS sales representative, Mr. Fischer could only promote Abilify for MDD, making any attempt to market Abilify to these physicians illegal off-label promotion.

233. Defendants continuously misled child and adolescent providers with false messaging, leading them to believe Abilify was appropriate for child and adolescent patients with depression symptoms and omitting information regarding the lack of safety and efficacy for that patient population. Rather, FDA warns against the use of Abilify for depression in children and adolescents.

234. In the context of Defendants' efforts to market Abilify to the elderly, Defendants' sales representatives routinely made misrepresentations to induce providers to prescribe Abilify for use in geriatric patients with dementia, notwithstanding the serious dangers associated with use of Abilify by such patients.

235. Defendants routinely marketed Abilify to nursing home providers by focusing on symptoms that they knew were present in patients with dementia, rather than Abilify's limited indications for use in adults. Indeed, Ellen Weaver-Bailey, Relator Ibanez's supervisor during his time in RCC, explicitly instructed her staff to sell to the symptoms of dementia in long-term care facilities, but never to use "the D word." In

doing so, sales representatives materially omitted the serious dangers associated with the use of Abilify in patients with dementia.

236. During his time in the RCC division, Relator Ibanez was directed to market Abilify to the Alois Alzheimer Center. Relator Ibanez's district business manager, ,Ellen Weaver-Bailey, directed him to have Dr. Bill Kasper, a Doctor of Pharmacy and BMS Medical Science Liaison, perform the "in-service" training session. Dr. Kasper presented the Abilify Schizophrenia & Bipolar I Disorder speaker's slide deck, and received numerous questions regarding the similarity of symptoms between dementia, Schizophrenia, and Bipolar I Disorder. Consistent with the BMS corporate message, Dr. Kasper told the staff that the efficacy of symptom control in the BMS studies would indeed help the center control their dementia patients with similar symptoms. Dr. Kasper never mentioned Abilify's Black Box warning for dementia patients.

237. During a 2008 regional sales strategy meeting in Columbus, Ohio, Relator Ibanez was involved in an ABS Breakout training session regarding "selling in the Nursing Home Environment." Terry McCurren, then-current BMS district business manager, led the session. He told the ABS team that it is not illegal to discuss or promote Abilify for the treatment of dementia if the physician asks an unsolicited question. Mr. McCurren also told the team that they should sell Abilify as "not contraindicated for dementia," intending to communicate that it was safe and effective to prescribe Abilify for patients suffering from dementia. This message misrepresents the safety of Abilify in patients with dementia, and materially omits the Black Box warning noting increased mortality risks in such patients.

238. In 2008 and 2009, the ABS sales force was encouraged to use the sales aid, "Adjunctive Use of Abilify for MDD," in nursing homes. The ABS sales force also used a sales aid, "Nursing Home Core Visual Age," which showed a picture of a 63 year-old nursing home patient named "Mary" with the prominent statement that "more than one third of nursing home residents have a diagnosis of MDD." ABS representatives were instructed to "paint the picture" of 63-year old "Mary" residing in a nursing home, notwithstanding the fact that nursing homes are rarely populated by 63-year olds at all, let alone those with MDD but without dementia. Rather than patients like the mythical "Mary," Defendants intended for providers to prescribe Abilify for the actual population in nursing homes—patients suffering from dementia, and not MDD.

239. Defendants thus continuously misled nursing homes and providers treating geriatric patients with false messaging, inducing them to believe Abilify was appropriate for the dementia symptoms of this patient population while omitting information about the lack of safety and efficacy for the elderly. At no time did Defendants truthfully reveal the very serious warnings related to the use of Abilify in the elderly population or that its own studies had not evaluated the use of Abilify in elderly patients. To the contrary, Defendants distributed their promotional materials and studies as if they were equally applicable to this vulnerable population.

240. With respect to all providers—including those who treated children and those who treated elderly patients—Defendants' sales representatives attempted to reach patients with diagnoses beyond those for which Abilify was indicated by highlighting symptoms associated with other diagnoses present in the target-providers' patient populations. Sales representatives also explicitly marketed Abilify for

unapproved uses, provided affirmatively misleading information, and omitted material critical safety and efficacy information.

241. For example, while working in ABS and targeting hospital providers who treated both adults and children, Mr. Smith frequently promoted Abilify to physicians to reduce the risk of suicide. Abilify was not approved for that use. In fact, it increased the risk of suicide in patients under 24 years of age.

242. Sales representatives were also encouraged to tie Abilify to the unapproved use of improving sleep habits. Relator Edwards' call notes from 2010 show that selling Abilify as a sleep aid was effective: when a provider expressed concern about the rates of akathisia and weight gain, Relator Edwards noted he was responsive to her pitch that Abilify would improve his patients' sleep habits.

243. As another example of false and misleading messaging, sales representatives would approach child/adolescent providers asking if they had female patients who report that they can't concentrate in school, are moody, and are preoccupied with their weight. They would then falsely advocate that Abilify would help with those issues, both in the short and long term.

244. Further, consistent with his training, Relator Ibanez marketed Abilify to psychiatric Nurse Practitioner Barbara Henry at the University of Cincinnati Department of Psychiatry, who treated oncology patients. Ibanez marketed Abilify as a drug that would maximize cancer patients' happiness during their last days, and as such should be "moved up the line of therapy," or prescribed immediately for cancer patients who did not have the time to wait for other treatments to fail before trying Abilify. Ibanez's marketing tactics were effective, and he noted in an October 22, 2008 call note

that Nurse Practitioner Barbara Henry, after six months of calls, “[f]inally agreed that ab would be good choice for her oncology patients with continued symptoms.”

245. Additionally, sales representatives were trained to market Abilify as an activator – to persuade the physician that it would make the geriatric patient "more interactive," or a child/adult patient more functioning or energetic. Sales representatives would often use this “activator” effect as a way of positioning Abilify against one of its main competitors, Seroquel, which can cause sedative effects. Such messaging was false and misleading because it implies without any substantiation that Abilify was specifically shown in clinical trials to be a safe and effective “activator” and that it was safer and more effective than Seroquel.

246. By way of further example of Defendants’ false and misleading messaging regarding the safety and efficacy of Abilify, BMS management trained sales representatives with many ways to sidestep or minimize a provider’s concerns regarding Abilify’s side effects. Akathisia, which is a movement disorder that creates a feeling of inner restlessness and compels a need to be in constant motion, was one of the more common side effects of Abilify, especially when used by patients with depression. It often presented an obstacle for sales. To work around providers’ concerns, Defendants instructed their sales representatives to tell physicians to “start low, go slow,” with the understanding that if a patient starts on a lower dose, the side effects might not lead to early discontinuation because the patient would be more likely to just get used to the feeling of unrest. Such a “start low, go slow” directive was false and misleading because it advocated dosages for which the drug was not approved or indicated and it implied

that “staring low and going slow” had been studied and approved as safe and effective, which was untrue.

247. In addition, sales representatives were trained to suggest that providers reduce the dosage by, for example, splitting the tablets, or using liquid Abilify and placing it in the juice of patients in nursing homes. Such sales tactics are false and misleading because they imply that such dosage alterations have been studied and approved as safe and effective, when in fact no such studies were done, and the dosage being recommended was outside the labeled dosages. Such sales pitches fall well-outside the package insert and FDA-approved marketing pieces, and as such constitute false and misleading statements.

248. Defendants' widespread use of false and misleading marketing messages induced providers to prescribe Abilify for off-label uses.

E. Illegal Inducements: BMS Speakers and Other Inducements.

249. During their tenure, Relators observed Abilify sales representatives creating and/or inviting providers to paid programs, including speaking engagements and lunches, to induce high quintile prescribers and their "key influencers" to continue to write Abilify prescriptions.

250. For example, BMS-paid speaker and high-prescriber, Dr. Amita Patel of Dayton, Ohio, promoted Abilify use for patients with pseudo-dementia and aggressive behavior. Dr. Patel posited that Abilify was neuro-protective in patients with dementia or depression, because dementia and depression have similar symptoms. Dr. Patel made clear that she would prescribe more Abilify based on the number of speaker

programs she was awarded. BMS engaged Dr. Patel for at least three speaking programs, on June 25, 2008, February 12, 2009, and December 10, 2009.

251. BMS sales representatives nominated and influenced the retention or termination of speakers in order to induce the prescribing of Abilify. Further, BMS's Medical Information department exercised no independent oversight over the off-label messages delivered by these speakers, as was required by the CIA. 2007 CIA, pp.29-30, Section III.L.

252. In 2008, BMS sales representatives Donald Conley and Jennifer Evans asked district business manager Dion Smith if Dr. Mahmood Rahman could be added to the district's speakers list notwithstanding that the district was at its maximum allowable number of speakers, and Dr. Rahman was not a local, national, or international thought leader. Smith called Regional Assistant Manager of Regional Operations, Keith Watters, and got Rahman added into district's speakers' pool based on Conley's and Evan's report that Rahman was the number one atypical market class prescriber in their territory and that Rahman mentioned that he wanted the title of speaker on his CV. Conley reported that a speaker title on Rahman's CV would result in more Abilify prescriptions, and Smith responded that a title on a CV for moving market share leads to a bonus. Later that year, the speaker list had to be reduced. Smith asked his district business manager counterpart in Columbus, Steve Rosi, to add Rahman to his list because he did not want to lose any of Rahman's prescriptions. When Rosi agreed and added Rahman to his list, Smith, Conley and Evans celebrated with high-fives all around, beginning already to plan the "Pinnacle" trip that they would receive based on Rahman's prescriptions. (Each year, BMS's highest performing sales

representatives were rewarded with "Pinnacle" trips—extravagant trips to exotic locations.)

253. By way of another example, BMS-paid speaker Dr. Geraldine Wu of Cincinnati, Ohio, was retained as a speaker for her prescribing volume. BMS representatives Marty Hensley and Karina Fischer reported to the district that Dr. Wu was retained because she was that territory's "number one writer of Abilify and atypical antipsychotics." The representatives made clear that Defendants would lose market share if she was dropped as a speaker because she would retaliate by not writing Abilify.

254. Conversely, Dr. Randy Sansone of Miamisburg, Ohio, who was an international thought leader, was dropped as a speaker by Smith in 2008 because he was not writing enough prescriptions. In addition, Smith was unhappy with Dr. Sansone's use of Abilify. That is, Abilify was approved for use to augment anti-depressant therapy and is indicated for patients who have failed multiple trials of monotherapy. Consistent with its indication, Dr. Sansone typically prescribed Abilify as a third or fourth-line therapy, rather than moving Abilify "up the line," as Abilify sales representatives were trained to sell it. This infuriated Smith, and he directed Relator Ibanez to clearly communicate to Dr. Sansone that BMS would not keep him as speaker if he did not change his prescription patterns.

255. Likewise, Dr. Michael Chan in Columbus, Ohio, was abruptly terminated as a BMS speaker in 2008 by district business manager Steve Rosi. Rosi told his district that Dr. Chan was not writing enough Abilify to warrant a contract and

that there were more worthy physicians who should be rewarded with a speaker's contract because they were writing higher volumes of Abilify.

256. During Relators' tenure at BMS, BMS did not follow its own protocols for nominating, recommending, or appointing speakers. In 2010, Relator Ibanez reported the violations noted above to BMS Compliance and Human Resources representatives, expressing his concern that the company was knowingly acting in violation of the law and of its CIA. Not only was nothing done to bring the company into compliance, Relator Ibanez suffered retaliation as a result of making that report.

257. Defendants offered physicians and "key influencers" incentives, including paid speaking engagements, paid lunches, expensive dinners, free samples, and other incentives, as an inducement to prescribe Abilify. For example, as part of their MDD promotional efforts, Defendants conducted "city-wide" dinner meetings. Such meetings were held at high-end venues, such as the restaurant at the Sanctuary Camelback Mountain Resort and Spa in Scottsdale, Arizona, and were designed in induce physicians to prescribe Abilify for MDD.

258. Defendants' conduct violated the Anti-Kickback Statute and known conditions of payment in government healthcare programs. Claims resulting from these violations are false claims.

F. Knowing Conduct Resulting in False Claims to Government Healthcare Programs.

259. Defendants knew that its practices resulted in claims to government healthcare programs and that those claims were subject to the conditions of payment of those programs: they knew that the natural, probable, and foreseeable consequence of their promotion of off-label uses of Abilify was that healthcare providers and pharmacies

would submit claims for payment to government payors for an off-label and noncovered and nonpayable use.

260. Defendants knew that off-label uses of Abilify are not covered by Medicaid, Medicare, or other government healthcare programs.

261. As a material condition of payment, only reasonable and necessary items and services are covered by government healthcare programs, and a drug is not "reasonable and necessary" if it is not safe and effective.

262. Unlabeled uses of a drug are presumptively not safe and effective and can only be covered in the circumstance that the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice.

263. Defendants knew that Abilify was not approved for use in children and adolescents for any indication at all prior to October 2007 and then only for extremely limited indications. Defendants knew that Abilify was expressly "not approved for use in pediatric patients with depression." Defendants further knew that its use by children and adolescents with depression was not supported as safe and effective by any major compendia, authoritative literature, or accepted standards of medical practice.

264. Defendants knew that the use of Abilify by children and adolescents with depression is instead associated with significant safety risks, which are highlighted by FDA-required warnings about such use.

265. Defendants also knew that Abilify was never given a specific indication for use by the elderly, *i.e.*, those 65 and older. Defendants knew that the

studies conducted to determine the safety and efficacy of Abilify for the treatment of Schizophrenia, Bipolar I Disorder, and MDD did not include sufficient numbers of subjects aged 65 and over to determine the safety and efficacy of the drug in that population.

266. In addition, Defendants knew that the safety and efficacy of Abilify for treating patients with psychosis associated with Alzheimer's disease had not been established, that Abilify was expressly "not approved for the treatment of patients with dementia-related psychosis," and that such use was not supported as safe and effective by any major compendia, authoritative literature, or accepted standards of medical practice.

267. Defendants knew that the use of Abilify by the elderly was instead associated with significant safety risks, which are highlighted by FDA-required warnings about such use.

268. Defendants knew that claims resulting from violations of the AKS are not covered by Medicaid, Medicare, or other government healthcare programs and that claims for payment for such uses were not covered and payable by any of these programs.

269. Defendants knew that the natural, probable, and foreseeable consequence of their offer and payment of illegal incentives to providers was that healthcare providers and pharmacies would submit claims for payment to government payors for more prescriptions of Abilify.

270. Notwithstanding these facts, Defendants misled providers through false and misleading statements and omissions that Abilify was safe and effective for

off-label uses in pediatric and geriatric patient populations and engaged in concerted efforts to induce physician referrals by providing remuneration in the forms of speakerships, lunches, dinners, and outings, in violation of the AKS.

271. Defendants knew that their actions were a substantial factor in the submission of claims for the payment of Abilify for government healthcare beneficiaries.

272. Defendants' false and misleading statements and omissions regarding the safety and efficacy of Abilify for off-label uses in pediatric and geriatric populations violate material conditions of payment of government healthcare programs and would have a natural tendency to influence the Government's decision to pay the resulting claims.

273. Further underscoring Defendants' knowledge of the illegal nature of their off-label marketing of Abilify is the fact that they were under the dictates of Corporate Integrity Agreements that resulted from essentially the same behavior even while they were directing that the behavior continue. Under their Corporate Integrity Agreements with the United States, and the dictates of government healthcare laws, Defendants were required to comply with the FDCA and the AKS.

274. Specifically, Defendants were required to review their call plans, survey their detailing materials, and ensure that Abilify representatives are not illegally promoting it for off-label uses. In addition to their ongoing obligations under the law, Defendants were required to annually certify that their activities were compliant.

275. Yet, Defendants did not diligently identify and remove inappropriate targets from their call lists, and instead directed its sales force to induce off-label prescriptions, including by inappropriately targeting child and adolescent providers and

long term care facilities, and by inducing providers to prescribe based on isolated symptoms rather than medically-indicated diagnoses. Knowing that they were legally prohibited from such sales tactics, Defendants nonetheless directed their use, intending that providers prescribe Abilify for off-label, non-compendia uses.

276. Rather than ensure that their sales activities were compliant, Defendants incentivized their Abilify sales force to illegally promote Abilify. Compensation, bonus, performance reviews, and, ultimately, continued employment was directly tied to attainment of calls of their call lists, including required calls on inappropriate targets. Moreover, as reflected in sales force communications and other training materials, Defendants directed their sales force to market depression on all targets, without regard to appropriateness of the provider's patients, as "[a]djunctive MDD in adults remains the largest opportunity for the brand moving forward."

277. Defendants did everything they could to induce increased sales, including by continuing to offer illegal incentives in violation of the AKS. Defendants knew that their illegal incentives would result in false claims to government healthcare programs. Indeed, Defendants would not employ hundreds of sales representatives to engage in off-label marketing and to offer illegal inducements to physicians if those efforts had no effect on prescriber practices.

278. Defendants also knew their actions resulted in false claims to government healthcare programs. The submission of false claims for payment resulting from Defendants' promotion of Abilify for off-label uses in pediatric and geriatric populations was not merely the foreseeable consequence of Defendants' actions, it was the intended result.

279. If Abilify is prescribed for a government healthcare beneficiary, it results in a claim for payment for the drug which is submitted by a pharmacy, often through a pharmacy benefits manager or through a government healthcare program contractor. Defendants knew that such claims were submitted to government healthcare programs for every government-insured patient who was prescribed Abilify. And Defendants specifically sought out for inclusion on their call lists providers who prescribed high volumes of drugs to government healthcare beneficiaries.

280. Defendants were well-aware that the targeted physicians' patients were government healthcare program beneficiaries, and they strategized their illegal marketing schemes to target the highest prescribers. Defendants' documents reflect that they well-knew (and indeed tracked) that government healthcare programs represented the most significant payor of Abilify. Indeed, Defendants' documents show that Defendants were aware that Medicaid was the primary payor for child and adolescent facilities, and that Medicare (whether through Part A or Part D) was the primary payor in long term care facilities (in one year, at least 75% of total beneficiaries nationally). And, in one document where the Abilify sales team discusses an approach to a child-adolescent home, it states "majority of child adolescent homes is Medicaid…Usually very easy to assume that patients are Medicaid patients."

281. Targeting providers with high numbers of government healthcare beneficiaries was such an integral part of Defendants' business plan that sales representatives were trained in the importance of government payors to Defendants' business. For example, when Relator Edwards was trained in selling to long-term-care facilities, BMS underscored the importance of understanding the details of government

payors because they were the "major payers" and "biggest funding source" for mental health. In addition, representatives were evaluated on their success in this area: Relator Edwards' 2009 year-end evaluation notes her skill at helping her team "identify the rate and frequency with which they should be calling on particular providers in order to drive commercial business while maintaining their Medicaid share." And in his 2008 evaluation, Relator Ibanez was specifically commended on his teamwork for having provided "OH and KY Medicaid info in order to identify Abilify sales opportunities."

282. Further highlighting Defendants' mandate to focus on government healthcare payors is a BMS training document from 2009 entitled, "LTC [long-term-care] Managed Health Care Overview," and subtitled, "Follow the Money." The document instructs sales representatives on Medicare Parts A and D and on Medicaid and identifies potential barriers related to those programs for physicians prescribing Abilify. It notes, for example, that "knowing which Part D plans Abilify is preferred on [is] crucial to our success with LTC…." The document even speaks to veterans who have Tricare coverage and describes Tricare, a government healthcare program, as "an insurance plan just like all the others." In addition, with respect to "child/adolescent facilities," the training document simply says, "Have Medicaid coverage." It describes, as many other of Defendants' documents do, that the primary payor in the long-term-care arena (by at least 75%) is the United States.

283. Defendants tracked the prescribing levels of all their target physicians, and tracked the government healthcare reimbursement breakdown of their target audiences for marketing of MDD use, to include child, adolescent, and geriatric providers, both in office and institutional settings. For example, one document contains

a list of managed care plans in Ohio and Kentucky, with a breakdown of total prescription in the market, total growth, total Abilify prescriptions, total Abilify market share, etc., for the three months prior to February 2010. The chart then breaks down Ohio Medicaid and Kentucky Medicaid Abilify sales by provider, including by specialty and quintile. To illustrate, Dr. Elliott Friedeman, the child/adolescent psychiatrist in Cincinnati who was targeted for inducement by way of dinner at his favorite restaurant as discussed above, was a Q5 prescriber on the Ohio Medicaid list, having issued a total of 149 Abilify prescriptions during those three months.

284. Defendants used the fact that government healthcare programs reimbursed for Abilify as a way to induce providers to prescribe the drug. For example, Relator Ibanez's call notes from September 5, 2008, show that Dr. Hamill, a psychiatrist in Chillicothe, Ohio, "talks a good game but use stinks." One of the ways Relator Ibanez tried to increase the physician's utilization was to "remind[] him of the excellent…formulary status" with two of the major government managed care plans.

285. In the years 2005 through 2013, Abilify's total reimbursement from Medicaid and non-Medicaid programs was more than $11 billion. The Medicaid-reimbursed portion of that number is over $9.7 billion.

286. Notwithstanding knowledge of the material conditions of payment of Abilify claims and their ongoing obligations under existing CIA's, Defendants engaged in a corporate practice to induce the sales of Abilify to government healthcare programs through illegal incentives and illegal promotion of off-label uses.

287. On information and belief, this conduct is occurring nationwide and has been occurring since 2005.

288. Every claim submitted to government healthcare programs for Abilify that resulted from Defendants' concerted efforts to market Abilify for off-label uses in pediatric and geriatric populations by engaging in false and misleading promotion as described herein constitutes a false claim in violation of the False Claims Act.

289. Every claim submitted to government healthcare programs for Abilify that resulted from Defendants' violations of the AKS constitutes a false claim in violation of the False Claims Act.

290. False claims to government programs are the direct, proximate, and intended result of Defendants' illegal schemes. Defendants knowingly caused the submission of these claims.

291. Moreover, these continued schemes have resulted in overpayments by government healthcare programs. Notwithstanding the terms of their CIAs or their obligations to report overpayments, Defendants have illegally retained these overpayments and continued their illegal conduct.

G. Retaliatory and Wrongful Termination of Relators.

1. <u>Wrongful Termination of Joseph Ibanez.</u>

292. On or about 2008, Relator Ibanez began raising compliance issues with his employer, objecting to inappropriate detailing and inappropriate call targets for the promotion of Abilify.

293. On or around December of 2009, for example, Relator Ibanez emailed the BMS legal department regarding a compliance concern from a paid BMS

speaker, Dr. Neil Richtand at the University of Cincinnati Department of Psychiatry, regarding the promotion of Abilify in the geriatric population.

294. Thereafter, in January 2010, Relator was contacted by the Gary Delvecchio, Director of Compliance for U.S. Pharmaceuticals, and participated in a conference call with Mr. Delvecchio and a lawyer for the Neuroscience Division in which he discussed Dr. Richtand's concerns and his own concerns about patterns and practices of off-label promotions occurring with Abilify. In follow-up to that conference call, Relator Ibanez participated in numerous phone calls and emails with Mr. Delvecchio regarding his concerns about false and misleading advertising/data presentations for both pediatric and geriatric use and unlawful/unsafe use of an antipsychotic such as Abilify in the geriatric patient population. In one of these emails, Relator Ibanez reported that, in a meeting discussing how to increase sales to a high quintile office where only patients 18 and under are seen, an OBS rep stated: "The Abilify message is not important…it's selling [ ] Abilify in the physician's office not [sic] matter their specialty."

295. After raising his concerns, Mr. Ibanez began to receive negative performance reviews and experience negative attention and other retaliatory conduct in the terms and conditions of his employment.

296. By way of example, on April 12, 2010, Relator Ibanez was counseled by his superior for failing to "embrace teamwork" by objecting to inappropriate call targets. In that memorandum, Relator Ibanez's manager Keith Watters stated:

Embraces Teamwork: (Not Meeting)

> Joe, since our 2009 restructuring, you have been very hesitant to embrace the new PFS targets. Since December 1, you have called me on a daily basis discussing your concern between PFS and OBS, and who should be calling on which targets. It seems as though you are very hesitant to work among your OBS colleagues with shared targets.

297. Mr. Watters also criticized that "Some of the emails you have sent to [BMS representative] Marty & [Otsuka representative] Alec are very direct and state that they should not be calling on these targets."

298. Mr. Watters' memorandum delivered other illegitimate criticisms of Relator Ibanez's performance.

299. After Relator Ibanez's concerns about illegal promotion activities went unaddressed, Relator contacted representatives of the United States to report this information.

300. The retaliatory conduct by BMS created a hostile work environment for Relator. The stress of this environment forced Relator to go on a health leave on or about May 2010.

301. While on leave, Relator continued to discuss compliance issues with the BMS Human Resources ("HR") representatives.

302. In response, HR informed him that they had begun investigating him for fraudulent sales calls.

303. The information regarding these supposed fraudulent calls were fabricated. Instead of permitting Mr. Ibanez to evaluate or rebut this information, BMS notified him that he was being terminated on or about July 16, 2010. Mr. Ibanez received his last paycheck from BMS through July 23, 2010.

304. Mr. Ibanez was terminated in retaliation for his actions to stop violations of governing laws and regulations which resulted in false claims to government healthcare programs.

2. Wrongful Termination of Relator Jennifer Edwards.

305. Relator Edwards experienced similar retaliatory conduct in Arizona. She began reporting her concerns about potential compliance issues relating to inappropriate call targets for Abilify on or about November 2, 2009.

306. In response, Ms. Edwards experienced negative attention and criticism of her performance, and her concerns were unaddressed.

307. Ms. Edwards and Mr. Ibanez had conferred over work email and work phones regarding their mutual concerns about inappropriate call targets and illegal promotion activities.

308. On or about April or May 2010, Mr. Ibanez also communicated to Ms. Edwards that he contacted the U.S. Attorney's Office in Boston, Massachusetts regarding Defendants' illegal practices.

309. Within days, on May 12, 2010, Ms. Edwards was informed she was being terminated. Like Mr. Ibanez, she was advised that they were investigating and had reached the conclusion that she had falsified sales calls.

310. These allegations are unsupported. However, Ms. Edwards was not given an opportunity to evaluate the allegations against her or rebut them. Rather, she was terminated.

311. Ms. Edwards's termination was in retaliation for her actions to stop violations of governing laws and regulations which resulted in false claims to government healthcare programs.

COUNT I

Violations of the Federal False Claims Act

312. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

313. The False Claims Act, 31 U.S.C. § 3729(a)(1)(A), (B), and (G) imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim or to an obligation to pay money to the government, or those who knowingly conceal, improperly avoid or decrease an obligation to pay money to the government. The False Claims Act, 31 U.S.C. § 3729(a)(1)(C) imposes liability on those who conspire to commit a violation of subparagraphs (A), (B), or (G).

314. From 2005 through present, Defendants knowingly caused false claims to be submitted to government healthcare programs by engaging in an off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify.

315. Defendants agreed and collaborated on illegal marketing and kickback schemes to induce increasing prescriptions of Abilify.

316. Defendants knew that these prescriptions were resulting in claims for payment to government healthcare programs.

317. Defendants' actions, if known, would have affected the United States and the States' decision to pay the resulting claims.

318. Defendants' actions violated material conditions of payment under government healthcare programs.

319. The resulting claims are noncovered and nonpayable and are false claims.

320. Defendants acted knowingly, as that term is used in the False Claims Act.

321. Defendants' knowing actions to cause the submission of false claims for payment to the United States violated 31 U.S.C. §3729(a)(1)(A).

322. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Abilify, knowing that such false claims would be submitted to government healthcare programs for reimbursement.

323. Defendants have also caused the states to submit false claims to the United States Government in Form CMS-64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program), which falsely certified that all drugs for which federal reimbursement was sought, including Abilify, were paid for in compliance with federal law. Claims for Abilify resulting from illegal off-label marketing and illegal kickback schemes are not covered and payable by federal programs.

324. In the furtherance of this scheme, Defendants also caused to be made or used false records or statements material to a false claim in violation of 31

U.S.C. § 3729(a)(1)(B). Each illegal promotion material used to promote a drug off-label was a false record or statement material to a false claim.

325. As a result of their violations, Defendants received overpayments from government healthcare programs and failed to return the money to the Government in a timely manner. Defendants' ongoing and knowing failure to report these overpayments violates the False Claims Act, 31 U.S.C. § 3729(a)(1)(G).

326. Defendants' concerted actions to conspire to cause the submission of false claims to government healthcare programs also violates the False Claims Act, 31 U.S.C. § 3729(a)(1)(C).

327. Because the United States would not have paid for services which it knew to have been the result of illegal marketing campaigns, the United States has been harmed in an amount equal to the value paid by the United States.

328. The United States Government has been damaged as a result of Defendants' conduct in violation of the False Claims Act in an amount to be determined at trial.

COUNT II

Violations of the California False Claims Act

329. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

330. The California False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. Cal. Gov. Code § 12651(a)(1)-(a)(2).

331. California's anti-kickback law, codified among the administrative provisions for the state's Medicaid program, made it a crime to "solicit[]," "receive[]," "offer[]," or "pay[] any remuneration ... directly or indirectly, overtly or covertly, in cash or in valuable consideration of any kind" to "purchase [] order or [] recommend the purchasing [] or ordering of any goods ... or merchandise" covered by Medi-Cal, California's Medicaid program. *See* Cal. Welf. & Inst. Code § 14107.2(a), (b).

332. To obtain reimbursements from Medi-Cal, pharmacies and other providers submitted a provider agreement, which unequivocally stated, directly above the provider's signature line, that "PROVIDER AGREES THAT COMPLIANCE WITH THE PROVISIONS OF THIS AGREEMENT IS A CONDITION PRECEDENT TO PAYMENT TO PROVIDER." That provider agreement also specified that the provider should not take any action or receive any benefit that is prohibited by state or federal law. The California Medicaid provider agreement further required a provider to "comply with all applicable provisions of Chapter 7 ... of the [state's] Welfare and Institutions Code," which contained California's anti-kickback law.

333. In addition to expressly conditioning payment on AKS compliance through the Medicaid provider agreement, California, through its Medicaid statutes, also linked reimbursement to providers not engaging in fraud, including kickback arrangements. Under Cal. Welf. & Inst. C. § 14107.11-(a)(2), Medi-Cal had authority to withhold payments based on evidence of "fraud or willful misrepresentation by a provider as defined in [Cal. Welf. & Inst. C. §] 14043.1," and § 14043.1(i), in turn, defined fraud to include "any act that constitutes fraud under applicable federal or state law."

334. Claims for payment to California that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

335. From 2005 to the present, Defendants knowingly caused false claims to be submitted to Medi-Cal by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

336. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment for Abilify, including, without limitation, Pharmacy, CMS-1500, knowing that such false claims would be submitted to Medi-Cal for payment.

337. Defendants' actions, if known, would have affected California's decision to pay the resulting claims.

338. Defendants' actions violated material conditions of payment under California's healthcare program.

339. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to California for payment or approval. Cal. Gov. Code § 12651(a)(1).

340. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce California to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

341. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to California. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to California in a timely manner.

342. California, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had California been aware of Defendants' unlawful conduct.

343. By reason of Defendants' concerted acts, California has been damaged in a substantial amount to be determined at trial.

COUNT III

Violations of the Colorado Medicaid False Claims Act

344. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

345. The Colorado False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. Colo. Rev. Stat. § 25.5-4-305(1)(a)-(1)(b).

346. To obtain reimbursements from Colorado Medicaid, pharmacies and other providers were required to submit a provider agreement. That agreement unequivocally stated that "PROVIDER UNDERSTANDS THAT NON-COMPLIANCE

COULD RESULT IN NO PAYMENT FOR SERVICES RENDERED." Pursuant to that agreement, the provider also expressly agreed to "comply with all federal and state civil and criminal statues, regulations and rules relating to the delivery of benefits to eligible individuals and to the submission of claims for such benefits." (emphasis added).

347. In addition to conditioning payments on providers agreeing to comply with federal laws like the AKS, Colorado's Medicaid regulations linked reimbursement to kickback compliance. Specifically, pursuant to program integrity regulations, Colorado Medicaid had the authority to withhold payments based on evidence that a provider had "not complied with applicable federal and state statutes and regulations" or had "engaged in false representation and/or fraud in submitting Medical Assistance program claims." 10 Co. Admin. C. §§ 2505-10-8.076.1(7)(b), (j), (i). Further, Colorado Medicaid's pharmacy regulations provided that reimbursement would be made only if certain conditions were met, including that "[t]he prescription is dispensed in accordance with applicable federal and state laws, rules, and regulations" that govern the operation of Medicaid. Id. § 2505-10-8.800.12.A(4).

348. Claims for payment to Colorado that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

349. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Colorado Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

350. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment for Abilify, including, without limitation, Pharmacy, CMS-1500, knowing that such false claims would be submitted to the Colorado Medicaid program for payment.

351. Defendants' actions, if known, would have affected Colorado's decision to pay the resulting claims.

352. Defendants' actions violated material conditions of payment under Colorado's healthcare program.

353. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Colorado for payment or approval. Colo. Rev. Stat. §25.5-4-304(3)(a).

354. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Colorado to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

355. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Colorado. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to Colorado in a timely manner.

356. Colorado, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had Colorado been aware of Defendants' unlawful conduct.

357. By reason of Defendants' concerted acts, Colorado has been damaged in a substantial amount to be determined at trial.

COUNT IV

Violations of the Connecticut False Claims Act

358. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

359. The Connecticut False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. General Statute 17.319(v) § 17b-301b.

360. Connecticut made it a felony both to pay and to receive kickbacks in connection with Medicaid-covered goods and services. Specifically, a person was "guilty of paying a kickback when he knowingly offers or pays any benefit, in cash or kind, to any person with intent to influence such person ... to purchase [or] order or [] recommend the purchasing [] or ordering of any goods [] or services for which a claim of [] reimbursement has been filed with a [] state or federal agency." Conn. Gen. Stat. § 53a-161d. Similarly, the state proscribed "knowingly solicit[ing], accept[ing] or agree[ing] to accept any benefit, in cash or in kind, from another person upon an agreement or understanding that such benefit will influence such person's conduct in relation to

referring an individual or arranging for the referral [] for the furnishing of any goods [] or services" to be paid for by a state or federal agency. Id. § 53a-161c.

361. To receive reimbursements from Connecticut Medicaid, providers, including pharmacies, were required to submit a provider enrollment application and execute a provider agreement. In completing the enrollment application, the provider signed a certification, certifying, inter alia, "that, if I am granted status as a provider for Connecticut [Medicaid], I expressly agree to the following: to abide by all applicable federal and state statutes and regulations ..." Further, paragraph 26 of Connecticut Medicaid's provider agreement required providers to "acknowledge[]" their understanding "that the prohibitions set forth in the [Medicaid] Act include[d] ... any giving or seeking of kickbacks, rebates, or similar remunerations." (emphasis added). Pursuant to paragraph 2 of that agreement, providers also agreed to "abide by and comply with all federal and state statutes, regulations, and policies pertaining to Provider's participation in [] Connecticut [Medicaid] Program."

362. In addition to conditioning reimbursement on providers not engaging in kickback relationships, Connecticut Medicaid similarly specified, by regulation, that payment was not due unless the goods or services were rendered in accordance with federal and state laws like the AKS. Specifically, regulations directed Connecticut Medicaid "not [to] make payment for any ... goods or services [] not ... furnished in accordance with federal and state statutes and regulations ...." Conn. Agencies Reg. § 17b-262-531(b) (emphasis added).

363. Claims for payment to Connecticut that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

364. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Connecticut Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

365. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment for Abilify, including, without limitation, Pharmacy, CMS-1500, knowing that such false claims would be submitted to Connecticut Medicaid for payment.

366. Defendants' actions, if known, would have affected Connecticut's decision to pay the resulting claims.

367. Defendants' actions violated material conditions of payment under Connecticut's healthcare program.

368. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Connecticut for payment or approval. General Statute 17.319(v) § 17b-301b.

369. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Connecticut to approve and pay such false and fraudulent claims. For example, each illegal promotion

material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

370. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Connecticut. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to Connecticut in a timely manner.

371. Connecticut, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had Connecticut been aware of Defendants' unlawful conduct.

372. By reason of Defendants' concerted acts, Connecticut has been damaged in a substantial amount to be determined at trial.

COUNT V

Violations of the Delaware False Claims and Reporting Act

373. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

374. The Delaware False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. Del. Code Ann. tit. 6, § 1201(a)(1)-(a)(2).

375. Compliance with federal and state healthcare laws, including the federal AKS and Delaware's anti-kickback statute, is a material condition of payment of claims submitted to the Delaware Medicaid program. 31 Del. Code § 1005(b); Contract for Items or Servs. Delivered to Del. Med. Assist. Prog. Eligibles in the Dep't of Health and Soc. Servs. ¶ 3 (2014).

376. Claims for payment to Delaware that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

377. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Delaware Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

378. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment for Abilify, including, without limitation, Pharmacy, CMS-1500, knowing that such false claims would be submitted to the Delaware Medicaid program for payment.

379. Defendants' actions, if known, would have affected Delaware's decision to pay the resulting claims.

380. Defendants' actions violated material conditions of payment under Delaware's healthcare program.

381. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Delaware for payment or approval. Del. Code Ann. tit. 6, § 1201(a)(1).

382. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Delaware to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

383. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Delaware. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to Delaware in a timely manner.

384. Delaware, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had Delaware been aware of Defendants' unlawful conduct.

385. By reason of Defendants' concerted acts, Delaware has been damaged in a substantial amount to be determined at trial.

COUNT VI

Violations of the Florida False Claims Act

386. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

387. The Florida False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval,

and those who make or use, or cause to be made or used, false records or statements material to a false claim. Fla. Stat. § 68.082(2)(a)-(2)(b).

388. Florida's anti-kickback law, codified as part of the state's Medicaid Provider Fraud statute, made it a felony to "knowingly solicit, offer, pay, or receive any remuneration, including any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in kind, ... in return for [] purchasing [] ordering or [] recommending ... any goods, [] item, or service for which payment may be made, in whole or in part, under the Medicaid program." Fl. Stat. § 409.920(2)(e). In addition, Florida's laws governing pharmacies also specified that it was "unlawful for any person to pay or receive any commission, bonus, kickback or rebate... with any ... organization, agency, or person, either directly or indirectly, for patients referred to a pharmacy." Id. § 465.185(1).

389. To receive reimbursement from Florida Medicaid, providers, including pharmacies, were required to sign a provider agreement with the state's Medicaid agency. See Fl. Stat. § 409.907. Pursuant to paragraph 3 of that agreement, the provider "agree[d] to comply with [] state [] and federal laws, as well as rules, regulations, and statements of policy applicable to the Medicaid program." Further, for providers who wished to submit claims electronically to Medicaid, Florida Medicaid attached certain conditions on its processing and paying electronic claims. Specifically, upon a provider's receipt of each electronic claim payment by Florida Medicaid, the provider "certifie[d] that the claim complie[d] ... with all federal and state laws."

390. In addition to requiring providers to certify compliance with federal and state laws like the AKS as a precondition for receiving Medicaid payments, Florida

also expressly linked reimbursement to compliance with such laws by statutes and policies. Pursuant to the state's Medicaid statutes, the state Medicaid agency was authorized to "make payments for ... services rendered to Medicaid recipients only to [providers] ... performing services or supplying goods in accordance with federal [and] state laws." Fl. Stat. § 409.907. Further, Florida's Medicaid Provider Manual defined "overpayment" to include any amount that was "paid as a result of ... unacceptable practices, fraud [or] abuse" or "paid for services or goods that were ... not provided in accordance with laws, regulations, contracts, or Medicaid policy." That Manual also stated the state Medicaid agency would "take steps to recover the overpayment" if it was "apparent that any Medicaid provider ha[d] received any [overpayment]."

391. Claims for payment to Florida that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

392. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Florida Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

393. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the Florida Medicaid program, knowing that such claims would be submitted to Florida for reimbursement.

394. Defendants' actions, if known, would have affected Florida's decision to pay the resulting claims.

395. Defendants' actions violated material conditions of payment under Florida's healthcare program.

396. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Florida for payment or approval. Fla. Stat. § 68.082(2)(a).

397. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Florida to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

398. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Florida. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to Florida in a timely manner.

399. Florida, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had Florida been aware of Defendants' unlawful conduct.

400. By reason of Defendants' concerted acts, Florida has been damaged in a substantial amount to be determined at trial.

COUNT VII

Violations of the Georgia Medicaid False Claims Act

401. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

402. The Georgia False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. Ga. Code Ann. § 49-4-168.1(a)(1)-(a)(2).

403. Section 106(E) of Georgia's Medicaid Manual expressly "prohibited" any "offer or payment of remuneration, whether direct, indirect, overt, covert, in cash or in kind, in return for the referral of a Medicaid [beneficiary]." Section 106(J) of that Manual further prohibited providers from "bill[ing]" Medicaid "for any services not performed or delivered in accordance with all applicable policies." In addition, section 405(E) of that Manual specifically authorized Georgia Medicaid to deny reimbursement for "[n]oncompliance with any ... applicable policies and procedures," and section 407(F) authorized the state to recoup reimbursement when a provider failed to "comply with all terms and conditions of participation related to the service(s) for which a claim has been paid."

404. To be eligible for payments from Georgia's Medicaid program, providers, including pharmacies, executed a Statement of Participation, which expressly "establishe[d] the means and terms of reimbursement between [Georgia Medicaid] and the [provider]." That statement also specified that Georgia Medicaid would only "reimburse for such claims, and in such amounts as meet the provision of ... applicable

federal and state laws, [HHS] regulations ... and the applicable terms and conditions ... published in [Georgia Medicaid's] Policies and Procedures Manuals and amendments thereto."

405. In addition, "in consideration of the right to submit payment claims [electronically]," a provider was required to "agree[]," "certif[y]," and "stipulate[]" that:

- it "shall abide by all Federal and State statutes, rules and regulations governing the Georgia Medicaid Program;"
- "any false claim or statement or concealment of or failure to disclose a material fact may be prosecuted under applicable Federal and/or State Law" because "payment of claims ... [was] from Federal and State funds,"
- "all electronic [] claims submissions by the Provider shall be true, accurate and complete, and [the] Provider's signature on the [statement] shall be binding as certification of such ..."

406. Claims for payment to Georgia that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

407. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Georgia Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

408. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the Georgia Medicaid program, knowing that such claims would be submitted to Georgia for reimbursement.

409. Defendants' actions, if known, would have affected Georgia's decision to pay the resulting claims.

410. Defendants' actions violated material conditions of payment under Georgia's healthcare program.

411. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Georgia for payment or approval. Ga. Code Ann. § 49-4-168.1(a)(1).

412. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Georgia to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

413. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Georgia. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to Georgia in a timely manner.

414. Defendants acted knowingly, as that term is used in the False Claims Acts of Georgia.

415. Georgia, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had Georgia been aware of Defendants' unlawful conduct.

416. By reason of Defendants' concerted acts, Georgia has been damaged in a substantial amount to be determined at trial.

COUNT VIII

Violations of the Hawaii False Claims Act

417. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

418. The Hawaii False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. Haw. Rev. Stat. § 661-21(a)(1)-(a)(2).

419. Compliance with federal and state healthcare laws, including the federal AKS, is a material condition of payment of claims submitted to the Hawaii Medicaid program. Haw. Rev. Stat. § 346-43.5; Code of Haw. §§ 17-1704, 7-1736; Haw. Medicaid Provider Manual § 2.8.2; Haw. State Medicaid Prog. Provider Agreement and Condition of Participation, pt. B, ¶ 1 & pt. C.

420. To obtain reimbursement from Hawaii's Medicaid program, providers were required to submit a provider agreement, pursuant to which the provider agreed to: "abide by the applicable provisions of the Hawaii State Medicaid Program set forth in the Hawaii Administrative Rules, Title 17, Subtitle 12, and applicable provisions

set forth in the Code of Federal Regulations (C.F.R.) related to the Medical Assistance Program." Hawaii State Medicaid Program Provider Agreement and Condition of Participation (Part B) at ¶ 1.

421. Claims for payment to Hawaii that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

422. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Hawaii Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

423. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the Hawaii Medicaid program, knowing that such claims would be submitted to Hawaii for reimbursement.

424. Defendants' actions, if known, would have affected Hawaii's decision to pay the resulting claims.

425. Defendants' actions violated material conditions of payment under Hawaii's healthcare program.

426. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Hawaii for payment or approval. Haw. Rev. Stat. § 661-21(a)(1).

427. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Hawaii to approve and pay such false and fraudulent claims. For example, each illegal promotion material

used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

428. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Hawaii. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to Hawaii in a timely manner.

429. Defendants acted knowingly, as that term is used in the False Claims Acts of Hawaii.

430. Hawaii, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had Hawaii been aware of Defendants' unlawful conduct.

431. By reason of Defendants' concerted acts, Hawaii has been damaged in a substantial amount to be determined at trial.

COUNT IX

Violations of Illinois False Claims Act

432. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

433. The Illinois False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval,

and those who make or use, or cause to be made or used, false records or statements material to a false claim. 740 Ill. Comp. Stat. 175/3(a)(1)(A)-(a)(1)(B).

434. To be eligible for payments from Illinois's Medicaid program, providers, including pharmacies, were required to submit a provider agreement pursuant to which the provider "agree[d], on a continuing basis, to comply with Federal standards specified in Title XIX and XXI of the Social Security Act and with all other applicable Federal and State laws []." The AKS, enacted as an addition to the Social Security Act, was one of the "applicable Federal [] laws" referenced in that provider agreement. That agreement also required the provider to "acknowledge[] that it [understood] the laws and handbook provisions regarding services and [to] certify that the services [complied] with such laws and handbook provisions." Finally, the provider "further acknowledge[d] that compliance with such laws and handbook provisions [was] a condition of payment for all claims submitted."

435. In addition to expressly conditioning payment on AKS compliance through its provider agreement, Illinois's Medicaid Handbook also specified that the State "actively monitor[ed] all claims for payments" to identify possible fraud, which include[d] claims that were for services not rendered in accordance with "civil and criminal" laws applicable to Medicaid. See Illinois Medicaid Handbook, Chap. 136.

436. Claims for payment to Illinois that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

437. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Illinois Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the

prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

438. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the Illinois Medicaid program, knowing that such claims would be submitted to Illinois for reimbursement.

439. Defendants' actions, if known, would have affected Illinois' decision to pay the resulting claims.

440. Defendants' actions violated material conditions of payment under Illinois' healthcare program.

441. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Illinois for payment or approval. 740 Ill. Comp. Stat. 175/3(a)(1)(A).

442. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Illinois to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

443. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Illinois. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to Illinois in a timely manner.

444. Defendants acted knowingly, as that term is used in the False Claims Acts of Illinois.

445. Illinois, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had Illinois been aware of Defendants' unlawful conduct.

446. By reason of Defendants' concerted acts, Illinois has been damaged in a substantial amount to be determined at trial.

COUNT X

Violations of the Ind. Code § 5-11-5.5-2(b)(1)-(b)(2)

447. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

448. The Indiana False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. Ind. Code § 5-11-5.5-2(b)(1)-(b)(2).

449. Indiana's anti-kickback statute, codified as part of the state's Medicaid statutes, made it a crime to "solicit[], offer[], or receive[] a kickback or bribe in connection with the furnishing of [any] items or services" covered by Medicaid "or the making or receipt of [any] payment" by Medicaid. Ind. Code § 12-15-24-2. Further, Chapter 13 of Indiana's Medicaid Provider Manual specifically identified "soliciting, offering, or receiving a kickback, bribe, or rebate" as an "example[] of [impermissible Medicaid] fraud."

450. Indiana Medicaid, in turn, required providers, including pharmacies, to submit a provider agreement. Pursuant to that agreement, the provider agreed to comply with all state and federal laws pertaining to the Medicaid program, i.e., including Indiana's anti-kickback statute and the AKS. Further, Indiana's Medicaid provider agreement also required providers to agree to render services in accordance with all applicable federal and state statutes and regulations as well as Indiana's Medicaid Provider Manual (which, as described above, identified kickback arrangements as a type of Medicaid fraud).

451. In addition to making AKS compliance a condition of payment through the provider agreement, Indiana's Medicaid laws and regulations also specified that kickback-tainted claims were not entitled to payment. For example, Indiana's Medicaid agency had the statutory authority to deny payment for claims when it determined that the "provider [had] violated a Medicaid statute or rule adopted under a Medicaid statute," Ind. Code § 12-15-22-1, such as the State's version of the AKS, id. § 12-15-24-2. Likewise, Indiana Medicaid regulations authorized the state to "deny payment" of claims "aris[ing] out of ... acts or practices ... violating any provisions of state or federal Medicaid law ..." 405 Ind. Admin. Code § 1-1-4(a)(6).

452. Claims for payment to Indiana that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

453. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Indiana Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the

prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

454. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the Indiana Medicaid program, knowing that such claims would be submitted to Indiana for reimbursement.

455. Defendants' actions, if known, would have affected Indiana's decision to pay the resulting claims.

456. Defendants' actions violated material conditions of payment under Indiana's healthcare program.

457. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Indiana for payment or approval. Ind. Code § 5-11-5.5-2(b)(1).

458. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Indiana to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

459. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Indiana. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to Indiana in a timely manner.

460. Defendants acted knowingly, as that term is used in the False Claims Acts of Indiana.

461. Indiana, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had Indiana been aware of Defendants' unlawful conduct.

462. By reason of Defendants' concerted acts, Indiana has been damaged in a substantial amount to be determined at trial.

COUNT XI

Violations of the Iowa False Claims Law

463. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

464. The Iowa False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. Iowa Law 15.5, § 685.2.

465. Compliance with federal and state healthcare laws, including the federal AKS and Iowa's anti-kickback statute, is a material condition of payment of claims submitted to the Iowa Medicaid program. Iowa Code Ann. § 249A.47 (2014); Iowa Dep't of Human Servs. Medicaid Provider Agreement § 1.4; Iowa Dep't of Human Servs. Policy Manual, I.C.1.

466. To obtain reimbursement from Iowa's Medicaid program, providers were required to submit a provider agreement, pursuant to which the provider agreed to:

"[c]omply with all applicable Federal and State laws, . . . including the Federal anti-kickback statute." Iowa Medicaid Provider Agreement § 1.4

467. Claims for payment to Iowa that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

468. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Iowa Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

469. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the Iowa Medicaid program, knowing that such claims would be submitted to Iowa for reimbursement.

470. Defendants' actions, if known, would have affected Iowa decision to pay the resulting claims.

471. Defendants' actions violated material conditions of payment under Iowa's healthcare program.

472. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Iowa for payment or approval. Iowa Law 15.5, § 685.2.

473. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Iowa to approve and pay such false and fraudulent claims. For example, each illegal promotion material used

to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

474. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Iowa. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to Iowa in a timely manner.

475. Defendants acted knowingly, as that term is used in the False Claims Acts of Iowa.

476. Iowa, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had Iowa been aware of Defendants' unlawful conduct.

477. By reason of Defendants' concerted acts, Iowa has been damaged in a substantial amount to be determined at trial.

COUNT XII

Violations of the Louisiana Medical Assistance Programs Integrity Law

478. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

479. The Louisiana False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or

approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. La. Rev. Stat. § 46:438.3(A)-(B).

480. Compliance with federal and state healthcare laws, including the federal AKS and Louisiana's anti-kickback statute, is a material condition of payment of claims submitted to the Louisiana Medicaid program. La. Rev. Stat. §§ 438.2, 46:437.11, -.14; 50 La. Admin. Code §§ 4145, 4147; La. Medicaid Prog. Manual §§ 1.1, 1.3; La. Provider Agreement, PE-50 Addendum § 10, 26, 27 (2013)**;** Louisiana General Information and Administration Provider Manual § 1.3, available at http://www.lamedicaid.com/provwebl/Providermanuals/manuals/GIA/GIA.pdf (authorizes denial of payment when providers have violated Medicaid laws, rules and policies).

481. To obtain reimbursement from Louisana's Medicaid program, providers were required to submit a provider agreement, pursuant to which the provider agreed to: "conduct my activities/actions in accordance with the Medical Assistance Program Integrity Law (MAPIL Louisiana R.S. Title 46, Chapter 3, Part VI-A) as required to protect the fiscal and programmatic integrity of the medical assistance programs … [and provide services and/or supplies that are] medically necessary and medically appropriate for each individual patient based on needs presented on the date the service is provided and/or delivered." Louisiana State Medicaid Program PE-50 Addendum - Provider Agreement at ¶¶ 9,10.

482. Claims for payment to Louisiana that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

483. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Louisiana Medicaid program by engaging in an illegal and

misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

484. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the Louisiana Medicaid program, knowing that such claims would be submitted to Louisiana for reimbursement.

485. Defendants' actions, if known, would have affected Louisiana's decision to pay the resulting claims.

486. Defendants' actions violated material conditions of payment under Louisiana's healthcare program.

487. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Louisiana for payment or approval. La. Rev. Stat. § 46:438.3(A).

488. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Louisiana to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

489. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Louisiana. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material

misrepresentations to government healthcare providers. Defendants failed to return the money to Louisiana in a timely manner.

490. Defendants acted knowingly, as that term is used in the False Claims Acts of Louisiana.

491. Louisiana, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had Louisiana been aware of Defendants' unlawful conduct.

492. By reason of Defendants' concerted acts, Louisiana has been damaged in a substantial amount to be determined at trial.

COUNT XIII

Violations of the Maryland False Health Claims Act

493. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

494. The Maryland False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. Md. Code. Ann., Health-Gen. § 2-602(a)(1)-(a)(2).

495. Maryland's anti-kickback law, codified as part of the state's Medicaid Fraud statutes, made it a felony to "solicit[], offer[], make[], or receive[] a kickback or bribe in connection with providing goods or services [valued at $1,000 or more in the aggregate] under [Medicaid]." Md. Crim. L. §§ 8-511; 8-516.

496. To receive reimbursements from Maryland Medicaid, pharmacies were required to have in effect a provider agreement with the state's Medicaid agency. See Code of Md. Reg. § 10.09.36.03. The Maryland Medicaid provider agreement, in turn, required the pharmacy to agree "to comply with all of the applicable requirements of the Maryland Medical Assistance Program" and to "acknowledge[]" its "responsibility to become familiar with those requirements."

497. In addition to conditioning Medicaid payments on AKS compliance through the provider agreement, Maryland's Medicaid regulations also expressly authorized the "withholding of payment" if it had been determined "that a provider [or] pharmacist ... has failed to comply with the applicable federal or State laws or regulations," such as the AKS and Maryland's version of the AKS. Code of Md. Reg. § 10.09.03.09.

498. Claims for payment to Maryland that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

499. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Maryland Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

500. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the Maryland Medicaid program, knowing that such claims would be submitted to Maryland for reimbursement.

501. Defendants' actions, if known, would have affected Maryland's decision to pay the resulting claims.

502. Defendants' actions violated material conditions of payment under Maryland's healthcare program.

503. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Maryland for payment or approval. Md. Code. Ann., Health-Gen. § 2-602(a)(1).

504. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Maryland to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

505. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Maryland. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to Maryland in a timely manner.

506. Defendants acted knowingly, as that term is used in the False Claims Acts of Maryland.

507. Maryland, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants,

paid claims that would not have been paid had Maryland been aware of Defendants' unlawful conduct.

508. By reason of Defendants' concerted acts, Maryland has been damaged in a substantial amount to be determined at trial.

COUNT XIV

Violations of the Massachusetts False Claims Act

509. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

510. The Massachusetts False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. Mass. Gen. Laws ch. 12, § 5B(1)-(2).

511. Massachusetts's anti-kickback laws, codified as among the statutes governing the state's Medicaid program, imposed both criminal and civil penalties for "solicit[ing]," "receiv[ing]," "offer[ing]," or "pay[ing] any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for ... purchas[ing], order[ing] or [] recommend[ing] purchasing [] or ordering of any good ... or item for which payment may be made in whole or in part" by Massachusetts Medicaid. Mass. Stat. 118E §§ 41 (criminal penalties), 44 (civil remedies).

512. To obtain reimbursements from Massachusetts Medicaid, providers, including pharmacies, were required to submit a provider agreement. Pursuant to that agreement, providers agreed to "comply with all state and federal

statutes, rules, and regulations applicable to the provider's participation in [Massachusetts Medicaid]."

513. In addition, Massachusetts Medicaid regulations also expressly conditioned reimbursement on providers complying with the AKS and the state's anti-kickback law. Specifically, all providers, including pharmacies, were required to "comply with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, specifically including but not limited to 42 U.S.C. 1320a-7b [the federal AKS]." 130 C.M.R. § 450.261. Further, in the event of non-compliance, the state Medicaid agency had the authority to "withhold payment to a provider" based on "any violations" or "credible allegations of fraud." Id. § 450.249(b)-(c).

514. Claims for payment to Massachusetts that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

515. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Massachusetts Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

516. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the Massachusetts Medicaid program, knowing that such claims would be submitted to Massachusetts for reimbursement.

517. Defendants' actions, if known, would have affected Massachusetts' decision to pay the resulting claims.

518. Defendants' actions violated material conditions of payment under Massachusetts' healthcare program.

519. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Massachusetts for payment or approval. Mass. Gen. Laws ch. 12, § 5B(1).

520. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Massachusetts to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

521. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Massachusetts. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to Massachusetts in a timely manner.

522. Defendants acted knowingly, as that term is used in the False Claims Acts of Massachusetts.

523. Massachusetts, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had Massachusetts been aware of Defendants' unlawful conduct.

524. By reason of Defendants' concerted acts, Massachusetts has been damaged in a substantial amount to be determined at trial.

COUNT XV

Violations of the Michigan Medicaid False Claims Act

525. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

526. The Michigan False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. Mich. Comp. Laws § 400.607(1).

527. Michigan's anti-kickback statute, enacted as part of the state's Medicaid False Claims Act, was an amendment to the Michigan's Social Welfare Act 280 of 1939. MI. Stat. § 400.604. That provision made it a felony to "solicit[], offer[], or receive[] a kickback or bribe in connection with the furnishing of goods or service for which payment is or may be made in whole or in part" by Michigan's Medicaid program. *Id*.

528. To be eligible for payments from Michigan's Medicaid program, pharmacies were required to execute a pharmacy provider enrollment and trading partner agreement and to certify that, "by signing this agreement," it "agree[d] to the [agreement's] conditions and provisions." Specifically, one of the conditions in that agreement was that pharmacy "agree[d] to comply with the provisions of ... Act No. 280 of the Public Acts of 1939, as amended," which included Michigan's Medicaid anti-kickback statute.

529. In addition to requiring pharmacies to certify that they would not engage in kickback arrangements through the provider agreement, Michigan's Medicaid program manuals also indicated that reimbursements were conditioned on compliance with applicable federal and state laws, including the AKS and Michigan's anti-kickback statute. For example, section 3.1 of the Michigan Medicaid's pharmacy manual provided that "applicable State and Federal laws ... must be observed by participating pharmacies."

530. Claims for payment to Michigan that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

531. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Michigan Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

532. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the Michigan Medicaid program, knowing that such claims would be submitted to Michigan for reimbursement.

533. Defendants' actions, if known, would have affected Michigan's decision to pay the resulting claims.

534. Defendants' actions violated material conditions of payment under Michigan's healthcare program.

535. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Michigan for payment or approval. Mich. Comp. Laws § 400.607(1).

536. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Michigan to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

537. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Michigan. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to Michigan in a timely manner.

538. Defendants acted knowingly, as that term is used in the False Claims Acts of Michigan.

539. Michigan, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had Michigan been aware of Defendants' unlawful conduct.

540. By reason of Defendants' concerted acts, Michigan has been damaged in a substantial amount to be determined at trial.

COUNT XVI

Violations of the Minn. Stat. § 15C.02(a)(1)-(a)(2)

541. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

542. The Minnesota False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. Minn. Stat. § 15C.02(a)(1)-(a)(2).

543. Pursuant to its Medicaid regulations, Minnesota classified kickback relationships in violation of the AKS as a type of "fraud" that was subject to administrative sanctions. See Minn. Rule §§ 9505.2165, 2210. The regulations defined "fraud" to include "a felony listed in [42 U.S.C. §] 1320a-7b(b)(3)(D), subject to any safe harbors established in [42 C.F.R. § 1001.952]," i.e., the federal AKS. Id. § 9505.2165-4(C).

544. To be eligible for reimbursement from Minnesota Medicaid, a participating provider, such as BioScrip, was required to execute a provider agreement. Pursuant to that agreement, the provider "agree[d] to ... comply with all federal and state statute and rules relating to the delivery of services [] and to the submission of claims for such services."

545. In addition to requiring providers to state in the provider agreement that they would comply with federal laws like the AKS, Minnesota's Medicaid statutes and regulations also conditioned providers' entitlement to payments with their compliance with the AKS. See Minn. Stat. § 256B.064; Minn. Rule § 9505.2215.

Specifically, the state Medicaid statute authorized the state Medicaid agency to impose sanctions for "any reason for which a vendor could be excluded from participation in the Medicare program under section 1128, 1128A, or 1866(b)(8) of the Social Security Act," which included a civil or criminal violation of the AKS. See Minn. Stat. § 256B.064-1a(7). The sanctions available to the state's Medicaid agency under that statute included "suspension or withholding of payments to a vendor." Id. § 256B.064-1b. Minnesota's Medicaid regulations (which, as noted above, defined AKS violation as "fraud") provided that the state Medicaid agency "shall seek monetary recovery from a vendor" if a Medicaid payment "was the result of fraud ... on the part of the vendor." Minn. Rule § 9505.2215-1A (emphasis added).

546. Claims for payment to Minnesota that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

547. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Minnesota Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

548. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the Minnesota Medicaid program, knowing that such claims would be submitted to Minnesota for reimbursement.

549. Defendants' actions, if known, would have affected Minnesota's decision to pay the resulting claims.

550. Defendants' actions violated material conditions of payment under Minnesota's healthcare program.

551. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Minnesota for payment or approval. Minn. Stat. § 15C.02(a)(1).

552. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Minnesota to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

553. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Minnesota. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to Minnesota in a timely manner.

554. Defendants acted knowingly, as that term is used in the False Claims Acts of Minnesota.

555. Minnesota, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had Minnesota been aware of Defendants' unlawful conduct.

556. By reason of Defendants' concerted acts, Minnesota has been damaged in a substantial amount to be determined at trial.

COUNT XVII

Violations of the Montana False Claims Act

557. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

558. The Montana False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. Mont. Code Ann. § 17-8-403(1)(a)-(1)(b).

559. Compliance with federal and state healthcare laws, including the federal AKS and Montana's anti-kickback statute, is a material condition of payment of claims submitted to the Montana Medicaid program. Mont. Code § 45-6-13; Admin. Rules of Mont. §§ 37.85.401, 37.85.501; Gen. Info. for Providers: Medicaid and Other Med. Assist. Programs at 3.8; Mont. Health Care Programs [Medicaid, HMK Plus/Children's Medicaid, and HMK/CHIP] and MHSP Provider Enrollment Agreement and Signature Page at 19.

560. To obtain reimbursement from Montana's Medicaid and other healthcare programs, providers were required to submit a provider enrollment agreement, pursuant to which the provider agreed to: "[c]omply with all applicable laws, rules and written policies pertaining to the Montana Medicaid Program (Medicaid) . . . "

561. Claims for payment to Montana that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

562. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Montana Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

563. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the Montana Medicaid program, knowing that such claims would be submitted to Montana for reimbursement.

564. Defendants' actions, if known, would have affected Montana's decision to pay the resulting claims.

565. Defendants' actions violated material conditions of payment under Montana's healthcare program.

566. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Montana for payment or approval. Mont. Code Ann. § 17-8-403(1)(a).

567. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Montana to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

568. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Montana. Defendants received overpayments from government healthcare programs

for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to Montana in a timely manner.

569. Defendants acted knowingly, as that term is used in the False Claims Acts of Montana.

570. Montana, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had Montana been aware of Defendants' unlawful conduct.

571. By reason of Defendants' concerted acts, Montana has been damaged in a substantial amount to be determined at trial.

COUNT XVIII

Violations of the Nev. Rev. Stat. § 357.040(1)(a)-(1)(b)

572. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

573. The Nevada False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. Nev. Rev. Stat. § 357.040(1)(a)-(1)(b).

574. Nevada's Medicaid programs prohibited kickback relationships by defining them as a type of fraud on Medicaid. Nevada's Medicaid Services Manual, a compilation of the state's Medicaid regulations, provided, at Chapter 3303, that it was fraud to "solicit[], receiv[e], offer, or pay any remuneration (including any kickback, bribe,

or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for, or to induce any person to ... purchase [] order [] or recommend the purchase [] or order of any item, service [or] good [] for which payment may be made, in whole or part, under Medicaid."

575. To receive reimbursements from Nevada's Medicaid program, providers, including pharmacies, were required both to submit a provider enrollment application and to execute a Nevada Medicaid and Nevada Check Up Provider Contract. As part of the enrollment application, the provider "declare[d]" its understanding "that payment of satisfaction of [its Medicaid] claims [would] be from federal and state funds and [] false claims, statements, documents or concealment of material facts [could] be prosecuted under federal and state laws." Further, pursuant to the Medicaid provider contract, the provider "agree[d]" to comply with "all applicable local, state and federal laws, statutes, rules, and regulations, as well as administrative policies and procedures set forth by [Nevada Medicaid]." In addition, the provider contract specified that Nevada Medicaid "agree[d] to provide payment" to the extent that the services were "rendered by Provider in accordance with federal and state law and the [] policies and procedures set forth in the Nevada Medicaid Services Manual."

576. Claims for payment to Nevada that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

577. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Nevada Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the

prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

578. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the Nevada Medicaid program, knowing that such claims would be submitted to Nevada for reimbursement.

579. Defendants' actions, if known, would have affected Nevada's decision to pay the resulting claims.

580. Defendants' actions violated material conditions of payment under Nevada's healthcare program.

581. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Nevada for payment or approval. Nev. Rev. Stat. § 357.040(2).

582. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Nevada to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

583. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Nevada. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to Nevada in a timely manner.

584. Defendants acted knowingly, as that term is used in the False Claims Acts of Nevada.

585. Nevada, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been had Nevada been aware of Defendants' unlawful conduct.

586. By reason of Defendants' concerted acts, Nevada has been damaged in a substantial amount to be determined at trial.

COUNT XIX

Violations of the New Jersey False Claims Act

587. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

588. The New Jersey False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. N.J. Stat. Ann. § 2A:32C-3(a)-(b).

589. New Jersey's State Medicaid Anti-Kickback Statute made it a crime to "solicit[], offer[], or receive[] any kickback, rebate, or bribe in connection with the furnishing of items or services for which payment is or may be made in whole or in part" by New Jersey's Medicaid program. N.J. Stat. § 30:4d-17(c).

590. To receive payments from New Jersey's Medicaid program, providers, including pharmacies, were required to execute a provider agreement. That agreement gave providers specific notice that "[t]here are Federal and State Statutes

and Regulations governing kickbacks and referral practices which may apply to you ... [including], but are not limited to: the Federal Medicare and Medicaid Anti-Kickback Statute (42 USC 1320A-7b(b)) ... the State Medicaid Anti-Kickback Statute (NJSA 30:4D-17(C) ..." The provider agreement further directed providers to "carefully review and understand these legal requirements and prohibitions" because, by "signing [that] agreement," providers gave their "representation[s] that there [was] compliance with all these requirements."

591. In addition, New Jersey's Medicaid regulations also conditioned reimbursement on providers' compliance with applicable federal and state laws like the AKS and New Jersey's Medicaid Anti-Kickback Statute. See N.J. Admin. Code § 10:49-5.5(a)(17). Specifically, the state Medicaid agency had the authority to withhold payment for "[c]laims for services, goods or supplies which are furnished, rendered, [], or ordered in violation of Federal and State civil or criminal statutes." *Id*.

592. Claims for payment to New Jersey that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

593. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the New Jersey Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

594. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the New Jersey Medicaid program, knowing that such claims would be submitted to New Jersey for reimbursement.

595. Defendants' actions, if known, would have affected New Jersey's decision to pay the resulting claims.

596. Defendants' actions violated material conditions of payment under New Jersey's healthcare program.

597. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to New Jersey for payment or approval. N.J. Stat. Ann. § 2A:32C-3(a).

598. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce New Jersey to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

599. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to New Jersey. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to New Jersey in a timely manner.

600. Defendants acted knowingly, as that term is used in the False Claims Acts of New Jersey.

601. New Jersey, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had New Jersey been aware of Defendants' unlawful conduct.

602. By reason of Defendants' concerted acts, New Jersey has been damaged in a substantial amount to be determined at trial.

COUNT XX

Violations of the New Mexico Medicaid False Claims Act and the New Mexico Fraud Against Taxpayers Act

603. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

604. The New Mexico False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. N.M. Stat. Ann. § 27-14-4(A) and (C).

605. Compliance with federal and state healthcare laws, including the federal AKS and New Mexico's anti-kickback statute, is a material condition of payment of claims submitted to the New Mexcio Medicaid program. N.M. Stat. §§ 30-44-7, 30-44-8, 27-11-3; N.M. Admin. Code §§ 7.1.5.9, 8.351.2 et seq.; N.M. Med. Assist. Div. Prog. Policy Manual, ch. 302, §§ 8.302.1.11, 8.302.1.20(B)(12); N.M. Med. Assist. Div. Provider Agreement §§ 1.1, 8.1 – 8.4.

606. To obtain reimbursement from New Mexico's Medicaid and other healthcare programs, providers were required to submit a provider participation agreement, pursuant to which the provider agreed to: "[a]bide by all federal, state, and

local laws, rules and regulations, including but not limited to, those laws, regulations, and rules applicable to providers of services under Title XIX (Medicaid) and Title XXI (SCHIP) of the Social Security Act." The provider further agreed that " [s]ubmission of false or miscoded claims or fraudulent representation may subject the PROVIDER to termination."

607. Claims for payment to New Mexico that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

608. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the New Mexico Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

609. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the New Mexico Medicaid program, knowing that such claims would be submitted to New Mexico for reimbursement.

610. Defendants' actions, if known, would have affected New Mexico's decision to pay the resulting claims.

611. Defendants' actions violated material conditions of payment under New Mexico's healthcare program.

612. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to New Mexico for payment or approval. N.M. Stat. Ann. § 27-14-4(A) and 44-9-3(A)(1).

613. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce New Mexico to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

614. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to New Mexico. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to New Mexico in a timely manner.

615. Defendants acted knowingly, as that term is used in the False Claims Acts of New Mexico.

616. New Mexico, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had New Mexico been aware of Defendants' unlawful conduct.

617. By reason of Defendants' concerted acts, New Mexico has been damaged in a substantial amount to be determined at trial.

COUNT XXI

Violations of the New York False Claims Act

618. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

619. The New York False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. N.Y. State Fin. Law § 189(1)(a)-(1)(b).

620. Compliance with federal and state healthcare laws, including the federal AKS and New York's anti-kickback statute, is a material condition of payment of claims submitted to the New York Medicaid program. N.Y. Soc. Serv. Law §§ 366-d, 366-f; 18 N.Y. Codes, Rules, and Reg. §§ 518.1, 515.2; N.Y. State Medicaid Prog.: Info. for all Providers: Gen. Policy at 26-27, 63; N.Y. State Medicaid Physician Request for Enrollment at 5.

621. To obtain reimbursement from New York's Medicaid and program, providers were required to submit a New York State Medicaid Enrollment Form, pursuant to which the provider agreed to "abide by all applicable Federal and State laws. . ."

622. Claims for payment to New York that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

623. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the New York Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

624. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the New York Medicaid program, knowing that such claims would be submitted to New York for reimbursement.

625. Defendants' actions, if known, would have affected New York's decision to pay the resulting claims.

626. Defendants' actions violated material conditions of payment under New York's healthcare program.

627. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to New York for payment or approval. N.Y. State Fin. Law § 189(1)(a).

628. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce New York to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

629. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to New York. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to New York in a timely manner.

630. Defendants acted knowingly, as that term is used in the False Claims Acts of New York.

631. New York, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had New York been aware of Defendants' unlawful conduct.

632. By reason of Defendants' concerted acts, New York has been damaged in a substantial amount to be determined at trial.

COUNT XXII

Violations of the North Carolina False Claims Act

633. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

634. The North Carolina False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. N.C. Gen. Stat. § 1-607(a)(1)-(a)(2).

635. Compliance with federal and state healthcare laws, including the federal AKS and North Carolina's anti-kickback statute, is a material condition of payment of claims submitted to the North Carolina Medicaid program. N.C. Gen. Stat. § 108A-63(g); 10A N.C. Admin Code §§ 22F.0201, 22F.0602, 22F.0604; N.C. Div. of Med. Assist.: Durable Med. Equip. and Supplies: Medicaid and Health Choice Clinical Coverage Policy No. 5A, § 7.1.

636. Claims for payment to North Carolina that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

637. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the North Carolina Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

638. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the North Carolina Medicaid program, knowing that such claims would be submitted to North Carolina for reimbursement.

639. Defendants' actions, if known, would have affected North Carolina's decision to pay the resulting claims.

640. Defendants' actions violated material conditions of payment under North Carolina's healthcare program.

641. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to North Carolina for payment or approval. N.C. Gen. Stat. § 1-607(a)(1).

642. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce North Carolina to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

643. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to North Carolina. Defendants received overpayments from government healthcare programs

for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to North Carolina in a timely manner.

644. Defendants acted knowingly, as that term is used in the False Claims Acts of North Carolina.

645. North Carolina, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had North Carolina been aware of Defendants' unlawful conduct.

646. By reason of Defendants' concerted acts, North Carolina has been damaged in a substantial amount to be determined at trial.

COUNT XXIII

Violations of the Oklahoma Medicaid False Claims Act

647. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

648. The Oklahoma False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. Okla. Stat. tit. 63, § 5053.1(B)(1)-(B)(2).

649. Oklahoma's anti-kickback statute, codified as part of the Oklahoma Medicaid Program Integrity Act, made it "unlawful for any person to willfully and knowingly ... solicit or accept a benefit, pecuniary benefit, or kickback in connection with

goods or services paid or claimed by a provider to be payable by [] Medicaid []." 56 Okla. Stat. § 1005(A)(6).

650. Oklahoma required providers, including pharmacies, to "have on file [] an approved Provider Agreement" with the state's Medicaid agency "[i]n order to be eligible for payment." Okla. Admin. C. § 317:30-3-2. A basic purpose of that agreement was to "assure[] compliance with all applicable Federal and State Regulations." *Id*. Specifically, pursuant to that agreement, providers certified they would "comply with all applicable Medicaid statutes, regulations, and policies, [as well as] properly promulgated rules of [Oklahoma's Medicaid agency]." The providers also acknowledged understanding that "all claims [would] be [] from federal and state funds" and any "false claims, statements or documents, or any concealment of a material fact [could] be prosecuted under applicable federal or state laws."

651. In addition, Chapter 2 of Oklahoma Medicaid's Provider Billing and Procedure Manual stated that the providers were not entitled to payments for "services not covered under the scope of [Oklahoma's Medicaid] program[]," which included services connected to kickback arrangements. Indeed, the Manual further specified that "claims [for such non-covered services] [would] be denied or payment [would] be recouped."

652. Claims for payment to Oklahoma that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

653. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Oklahoma Medicaid program by engaging in an illegal and

misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

654. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the Oklahoma Medicaid program, knowing that such claims would be submitted to Oklahoma for reimbursement.

655. Defendants' actions, if known, would have affected Oklahoma's decision to pay the resulting claims.

656. Defendants' actions violated material conditions of payment under Oklahoma's healthcare program.

657. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Oklahoma for payment or approval. Okla. Stat. tit. 63, § 5053.1(B)(1).

658. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Oklahoma to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

659. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Oklahoma. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material

misrepresentations to government healthcare providers. Defendants failed to return the money to Oklahoma in a timely manner.

660. Defendants acted knowingly, as that term is used in the False Claims Acts of Oklahoma.

661. Oklahoma, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had Oklahoma been aware of Defendants' unlawful conduct.

662. By reason of Defendants' concerted acts, Oklahoma has been damaged in a substantial amount to be determined at trial.

COUNT XXIV

Violations of the Rhode Island False Claims Act

663. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

664. The Rhode Island False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. R.I. Gen. Laws § 9-1.1-3(a)(1)-(a)(2).

665. Compliance with federal and state healthcare laws, including the federal AKS and Rhode Island's anti-kickback statute, is a material condition of payment of claims submitted to the Rhode Island Medicaid program. R.I. Gen. Laws §§ 40-8.2-3(a)(2), 40-8.2-5; Code of R.I. Rules § 15-040-08; R.I. Dept. of Hum. Serv. Code of

Rules §§ 0300.40.15, 0300.40.20; State of R.I. Exec. Off. of Health and Hum. Serv. Provider Agreement Form §§ 1, 15.

666. To obtain reimbursement from Rhode Island's Medicaid and other healthcare programs, providers were required to submit a provider enrollment agreement, pursuant to which the provider agreed to: "follow all laws, rules, regulations, certification standards, policies and amendments including but not limited to the False Claims Act and HIPAA, that govern the Rhode Island Medicaid Program as specified by the Federal Government and the State of Rhode Island."

667. Claims for payment to Rhode Island that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

668. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Rhode Island Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

669. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the Rhode Island Medicaid program, knowing that such claims would be submitted to Rhode Island for reimbursement.

670. Defendants' actions, if known, would have affected Rhode Island's decision to pay the resulting claims.

671. Defendants' actions violated material conditions of payment under Rhode Island's healthcare program.

672. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Rhode Island for payment or approval. R.I. Gen. Laws § 9-1.1-3(a)(1).

673. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Rhode Island to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

674. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Rhode Island. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to Rhode Island in a timely manner.

675. Defendants acted knowingly, as that term is used in the False Claims Acts of Rhode Island.

676. Rhode Island, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had Rhode Island been aware of Defendants' unlawful conduct.

677. By reason of Defendants' concerted acts, Rhode Island has been damaged in a substantial amount to be determined at trial.

COUNT XXV

Violations of the Tennessee Medicaid False Claims Act

678. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

679. The Tennessee False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. Tenn. Code Ann. § 4-18-103(a)(1)-(a)(2).

680. Compliance with federal and state healthcare laws, including the federal AKS, is a material condition of payment of claims submitted to the Tennessee Medicaid program. Tenn. Code § 71-1-120; Tenn. Rules and Reg. §§ 1200-13-1-.05, 1200-13-1-.21; State of Tenn., Dep't of Fin. and Admin., Med. Assist. Participation Agreement (Medicaid/TennCare Title XIX Program) for Inpatient and Outpatient Hospital Serv. §§ I(D), I(E), III(A), III(F).

681. To obtain reimbursement from Tennessee's Medicaid program, providers were required to submit a provider participation agreement, pursuant to which the provider agreed to: "[c]omply with all contractual terms and Medicaid policies as outlined in Federal and State rules and regulations and Medicaid provider manuals and bulletins."

682. Claims for payment to Tennessee that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

683. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Tennessee Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

684. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the Tennessee Medicaid program, knowing that such claims would be submitted to Tennessee for reimbursement.

685. Defendants' actions, if known, would have affected Tennessee's decision to pay the resulting claims.

686. Defendants' actions violated material conditions of payment under Tennessee's healthcare program.

687. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Tennessee for payment or approval. Tenn. Code Ann. § 4-18-103(a)(1).

688. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Tennessee to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

689. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Tennessee. Defendants received overpayments from government healthcare programs

for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to Tennessee in a timely manner.

690. Defendants acted knowingly, as that term is used in the False Claims Acts of Tennessee.

691. Tennessee, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had Tennessee been aware of Defendants' unlawful conduct.

692. By reason of Defendants' concerted acts, Tennessee has been damaged in a substantial amount to be determined at trial.

COUNT XXVI

Violations of Tex. Hum. Res. Code Ann. § 36.002(1)

693. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

694. The Texas False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. Tex. Hum. Res. Code Ann. § 36.002(1)-(13).

695. Texas imposed both civil and criminal penalties on kickbacks in connection with the state's Medicaid program. The civil provision, codified as part of the state's Medicaid statutory scheme, provided both damages and penalties for "solicit[ing]," "receiv[ing]," "offer[ing]," or "pay[ing], directly or indirectly, overtly or

covertly any remuneration, including any kickback, bribe or rebate, in cash or in kind to induce a person to purchase, [] order[ing] or [] recommend the purchase [] or ordering of any good ... or item for which payment may be made, in whole or in part, under [Texas's Medicaid] program." Tex. Hum. Res. C § 32.039(b)1-b–1e. The criminal provision, in turn, made it a criminal offense to "knowingly pay[], charge[], solicit[], accept[], or receive[], in addition to an amount paid under the Medicaid program, a gift, money, a donation or other consideration as a condition to the provision of a service or product." Tex. Penal C. § 35A.02(5).

696. To obtain reimbursements from Texas Medicaid, pharmacies, such as BioScrip, were required to execute an agreement with the state. That agreement expressly required the pharmacy to "comply with all Texas and federal laws that regulate fraud, abuse, and waste in health care and the Medicaid [] program []." It also stated that, "by signing this Contract," the pharmacy was "confirm[ing] that [it has] read, understood, and will comply with the terms of this Contract and the applicable requirements of the Medicaid [] program[]."

697. In addition, Texas Medicaid statutes expressly linked reimbursements to providers complying with prohibitions on kickbacks like the state's anti-kickback law. Specifically, if it found non-compliance with the civil anti-kickback provision, Texas's Medicaid agency was entitled to recover "the amount paid ... as result of the [kickback] violation and interest on that amount," as well as penalties. See Tex. Hum. Res. C § 32.039(C).

698. Claims for payment to Texas that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

699. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Texas Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

700. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the Texas Medicaid program, knowing that such claims would be submitted to Texas for reimbursement.

701. Defendants' actions, if known, would have affected Texas' decision to pay the resulting claims.

702. Defendants' actions violated material conditions of payment under Texas' healthcare program.

703. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Texas for payment or approval. Tex. Hum. Res. Code Ann. 36.002(13).

704. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Texas to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

705. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Texas. Defendants received overpayments from government healthcare programs for orders

for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to Texas in a timely manner.

706. Defendants acted knowingly, as that term is used in the False Claims Acts of Texas.

707. Texas, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been had Texas been aware of Defendants' unlawful conduct.

708. By reason of Defendants' concerted acts, Texas has been damaged in a substantial amount to be determined at trial.

COUNT XXVII

Violations of the Virginia Fraud Against Taxpayers Act

709. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

710. The Virginia False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. Va. Code Ann. § 8.01-216.3(A)(1)-(A)(2).

711. Virginia's anti-kickback law was codified as part of the state's Medicaid statutory scheme. See Va. Code § 32.1-315. Specifically, that provision made it a felony to "knowingly and willfully solicit[] or receive[]" or "offer[] or pay[] any remuneration, including any kickback, bribe, or rebate, directly or indirectly, overtly or

covertly, in cash or in-kind ... in return for purchasing, [] ordering, or [] recommending purchasing [] or ordering any goods, [] service, or item" covered by the state's Medicaid program. Id. § 32.1-315(A), (B).

712. To obtain Medicaid reimbursements from Virginia, pharmacies and other providers were required to submit a Participation Agreement. As part of that agreement, the pharmacy stated it understood (i) that it was "responsible for the presentation of true, accurate, and complete information on all invoices/claims submitted to [the state Medicaid program];" and (ii) that "payment and satisfaction of these claims [would] be from federal and state funds and that false claims, statements, documents, or concealment of material fact [could] be prosecuted under applicable federal and state laws." In addition, each time a pharmacy submitted a claim to Virginia's Medicaid program, it was required to sign a certification averring that the information in the claim was "true accurate and complete" and the claim did not involve any "concealment of material fact."

713. Claims for payment to Virginia that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

714. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Virginia Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

715. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the Virginia Medicaid program, knowing that such claims would be submitted to Virginia for reimbursement.

716. Defendants' actions, if known, would have affected Virginia's decision to pay the resulting claims.

717. Defendants' actions violated material conditions of payment under Virginia's healthcare program.

718. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Virginia for payment or approval. Va. Code Ann. § 8.01-216.3(A)(1).

719. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Virginia to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

720. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Virginia. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to Virginia in a timely manner.

721. Defendants acted knowingly, as that term is used in the False Claims Acts of Virginia.

722. Virginia, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had Virginia been aware of Defendants' unlawful conduct.

723. By reason of Defendants' concerted acts, Virginia has been damaged in a substantial amount to be determined at trial.

COUNT XXVIII

Violations of the Washington Health Care False Claim Act.

724. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

725. The Washington False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. RCW 48.80 § 030.

726. Washington's state anti-kickback statute made it a felony for "any person" to "solicit[] or receive[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind .... in return for purchasing [] ordering, or arranging for or recommending purchasing [] or ordering any goods ... or item" that may be covered by Washington's Medicaid program. Wash. Rev. Code Ann. § 74.09.240(1)(b).

727. To be eligible for Medicaid reimbursement in Washington, providers, including pharmacies, were required to execute a Core Provider Agreement. Pursuant to paragraph 1 of that agreement, the provider agreed "to [be] subject to and

[to] comply with all federal and state laws, rules, and regulations ...." Further, pursuant to paragraph 15 of that agreement, the provider certified that it would "abide by the terms of this Agreement including all applicable federal and state statutes, rules, and policies."

728. In addition, Washington Medicaid regulations also conditioned payment on compliance with applicable federal and state laws like the AKS and the state anti-kickback statute. *See* Wash. Admin. Code § 182-502-0016. Specifically, to "be paid for [] services" under Washington's Medicaid program, "a provider must ... [p]rovide all services according to federal and state laws and rules." *Id*.

729. Claims for payment to Washington that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

730. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Washington Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

731. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the Washington Medicaid program, knowing that such claims would be submitted to Washington for reimbursement.

732. Defendants' actions, if known, would have affected Washington's decision to pay the resulting claims.

733. Defendants' actions violated material conditions of payment under Washington's healthcare program.

734. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Washington for payment or approval. RCW 48.80 § 030.

735. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Washington to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

736. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Washington. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to Washington in a timely manner.

737. Defendants acted knowingly, as that term is used in the False Claims Acts of Washington.

738. Washington, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had Washington been aware of Defendants' unlawful conduct.

739. By reason of Defendants' concerted acts, Washington has been damaged in a substantial amount to be determined at trial.

COUNT XXIX

Violations of the Wisconsin False Claims for Medical Assistance Law

740. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

741. The Wisconsin False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. Wis. Stat. § 20.931(2)(a)-(2)(b).

742. Wisconsin's anti-kickback law, codified as part of Wisconsin's Medicaid fraud statute, classified as a felony the "solicitation," "receipt," "offer" or "payment" of any kickbacks in connection with the state's Medicaid program. See Wisc. Stat. § 49.49(2) (re-codified in 2013 as Wis. Stat. § 946.91(3)).

743. To be eligible for reimbursement from Wisconsin's Medicaid program, providers, including pharmacies, were required to execute a provider agreement. Pursuant to that agreement, the provider acknowledged that "by submitting claims [to] Wisconsin Medicaid," it was "subject to those terms, conditions, and restrictions" relevant to Wisconsin Medicaid. As part of that agreement, the provider also acknowledged its understanding that those "terms, conditions, and restrictions" could be "listed in [the provider agreement]" or "set forth in applicable law" and that the terms, conditions, and restrictions applied to its conduct "regardless [of] whether the provider [had] actual knowledge of those terms, conditions, and restrictions."

744. In addition, by regulation, Wisconsin Medicaid expressly linked its payment for claims on the underlying services being in compliance with applicable federal and state laws, including the AKS and Wisconsin's anti-kickback statute. *See* Wis. Admin. C. D.H.S. § 107.02(2)(a). Specifically, that regulation defined "[s]ervices which fail[ed] to comply with ... state and federal statutes" as "non-reimbursable services." Id.

745. Claims for payment to Wisconsin that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

746. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the Wisconsin Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

747. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the Wisconsin Medicaid program, knowing that such claims would be submitted to Wisconsin for reimbursement.

748. Defendants' actions, if known, would have affected Wisconsin's decision to pay the resulting claims.

749. Defendants' actions violated material conditions of payment under Wisconsin's healthcare program.

750. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Wisconsin for payment or approval. Wis. Stat. § 20.931(2)(a).

751. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce Wisconsin to approve and pay such false and fraudulent claims. For example, each illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

752. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to Wisconsin. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to Wisconsin in a timely manner.

753. Defendants acted knowingly, as that term is used in the False Claims Acts of Wisconsin.

754. Wisconsin, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had Wisconsin been aware of Defendants' unlawful conduct.

755. By reason of Defendants' concerted acts, Wisconsin has been damaged in a substantial amount to be determined at trial.

COUNT XXX

Violations of the District of Columbia False Claims Act

756. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

757. The District of Columbia False Claims Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. D.C. Code § 2-308.14(a)(1)-(a)(2).

758. The District of Columbia's ("D.C.") Medicaid Fraud Prevention Statute included anti-kickback provisions. *See* D.C. Code Ann. § 4-802. That statute made it a crime to "solicit, accept, [] agree to accept," or "confer, offer, or agree to confer or offer any type of remuneration for ... recommending the purchase [] or order of any good [] or item for which payment may be made under [D.C.'s] Medicaid program." *Id*. § 4-802(c)-(d).

759. To obtain reimbursements under D.C.'s Medicaid program, providers, including pharmacies, were required to execute a provider agreement. That agreement expressly conditioned payment on compliance with applicable federal and local laws such as the AKS and D.C.'s anti-kickback law, providing, specifically, that "if the [D.C. Medicaid agency] determine[d] that a provider [] failed to comply with the applicable Federal or District law or rule," the agency could "withhold all or part of the provider's payments."

760. Claims for payment to the District of Columbia that resulted from illegal kickbacks and illegal promotion of Abilify for noncovered and nonpayable uses are false claims.

761. From 2005 to the present, Defendants knowingly caused false claims to be submitted to the District of Columbia Medicaid program by engaging in an illegal and misleading off-label marketing campaign and illegal kickback schemes to induce the prescribing of Abilify, in knowing violation of material conditions of payment of those programs.

762. Defendants knowingly caused pharmacies and other healthcare providers to submit false claims for payment to the District of Columbia Medicaid program, knowing that such claims would be submitted to the District of Columbia for reimbursement.

763. Defendants' actions, if known, would have affected the District of Columbia's decision to pay the resulting claims.

764. Defendants' actions violated material conditions of payment under the District of Columbia's healthcare program.

765. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to the District of Columbia for payment or approval. D.C. Code § 2-308.14(a)(1).

766. By virtue of the acts described above, Defendants knowingly caused to be made or used false records and statements to induce the District of Columbia to approve and pay such false and fraudulent claims. For example, each

illegal promotion material used to promote the off-label use of Abilify was a false record or statement made or used to obtain approval or payment of a false claim.

767. By virtue of the acts described above, Defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the District of Columbia. Defendants received overpayments from government healthcare programs for orders for Abilify resulting from their illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the District of Columbia in a timely manner.

768. Defendants acted knowingly, as that term is used in the False Claims Acts of the District of Columbia.

769. The District of Columbia, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had the District of Columbia been aware of Defendants' unlawful conduct.

770. By reason of Defendants' concerted acts, the District of Columbia has been damaged in a substantial amount to be determined at trial.

CLAIMS ON BEHALF OF RELATORS PERSONALLY

COUNT XXXI

Retaliation of Relators in Violation of the False Claims Act, 31 U.S.C. § 3730(h)

771. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

772. As alleged in above, Relators engaged in lawful acts in furtherance of efforts to stop one or more violations of 31 U.S.C. § 3729.

773. Because of Relators' lawful acts, Relators were subjected to discrimination in the terms and conditions of their employment by BMS, including but not limited to their wrongful termination.

774. The Defendant's discrimination against Relators was a violation of 31 U.S.C. § 3730(h).

775. As a consequence of Defendant's violation of 31 U.S.C. § 3730(h), Relators suffered damages.

COUNT XXXII

Retaliation and Wrongful Discharge of Joseph Ibanez in Violation of the Ohio Whistleblower Statute, Ohio Rev. Code Ann. § 4113.52, Public Policy, and Common Law

776. The allegations in paragraphs are realleged as if fully set forth herein.

777. Relator Ibanez, during the course of his employment, became aware that the Defendant was in violation of federal laws in regard to its promotion of the drug Abilify.

778. Relator took steps to advise BMS management and other personnel of his concerns that its promotional campaigns were not compliant with federal healthcare laws and to stop violations of the federal and state FCAs.

779. Further, Relator took steps to inform the United States of his concerns that BMS practices were not compliant with federal healthcare laws.

780. As a direct and proximate consequence of his efforts, Relator Ibanez suffered retaliatory conduct by Defendant and was ultimately terminated.

781. BMS lacked an overriding legitimate business objective for terminating Relator's employment. To the contrary, Relator's termination was due to his internal reporting and objections to BMS conduct.

782. There is a clear public policy in the State of Ohio favoring the protection of whistleblowers from retaliatory acts by their employers, manifested in Ohio Rev. Code Ann. § 4113.52. There is also a clear public policy in the State of Ohio favoring adherence to federal statutes.

783. Permitting employers such as BMS to discharge employees such as Relator for internal reporting of violations of federal statutes would jeopardize these public policies.

784. Relator was retaliated against and wrongfully discharged in violation of Ohio law, as reflected by both statute and common law, including but not limited to the Ohio Whistleblower Statute, Ohio Rev. Code Ann. § 4113.52.

COUNT XXXIII

Retaliation and Wrongful Discharge of Jennifer Edwards in Violation of the Arizona Employment Protection Act, Arizona Revised Code § 23-1501, Public Policy, and Common Law

785. The allegations in paragraphs are realleged as if fully set forth herein.

786. Relator Edwards, during the course of her employment, became aware that the Defendant was in violation of federal and comparable state laws in regard to its illegal promotion of the drug Abilify. Such laws would include, without limitation, laws governing Medicaid coverage and Arizona statutes, A.R.S. § 36-2918 and §36-2957.

787. Relator took steps to disclose to BMS management and other personnel of her concerns that its promotional campaigns were not compliant with healthcare laws, and to stop violations of the federal and state FCAs.

788. As a direct and proximate consequence of her efforts, Relator Edwards suffered retaliatory conduct by Defendant and was ultimately terminated.

789. The Arizona Employment Protection Act protects employees from the retaliatory acts of their employers for reporting violations of state laws. A.R.S. § 23-1501 (b), (c). There is a clear public policy in the State of Arizona favoring the protection of whistleblowers from retaliatory acts by their employers, and manifested by such Article.

790. Relator was retaliated against and wrongfully discharged in violation of Arizona law, as reflected by both statute and common law, including but not limited to the Arizona Employment Protection Act, A.R.S.§ 23-1501.

PRAYER FOR RELIEF

WHEREFORE, Relators request:

A. That the Court enter judgment against the Defendants in an amount equal to three times the amount of damages the United States Government has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each action in violation of 31 U.S.C. § 3729, and the costs of this action, with interest, including the costs to the United States Government for its expenses related to this action;

B. That in the event the United States Government intervenes in this action, Relators be awarded 25% of the proceeds of the action or the settlement of any such claim;

C. That in the even the United States Government does not proceed with this action, Relators be awarded 30% of the proceeds of this action or the settlement of any such claim;

D. That the Court enter judgment against the Defendants in the maximum amount of damages available under the False Claims Acts of the Plaintiff States over which the Court accepts jurisdiction, to include any multipliers provided in such Acts;

E. That the Court enter judgment against the Defendants for the maximum amount of civil penalties in favor of the Plaintiff States, together with the Plaintiff States' costs of this action;

F. That the Relators be awarded, under the False Claims Acts of the Plaintiff States, the maximum share permitted by law of all amounts recognized by those Acts as a consequence of this action;

G. That the Relators be awarded all damages caused by Defendant BMS's retaliation and wrongful termination of them, including but not limited to two times the amount of back pay owed to them, interest on such back pay, lost benefits, compensatory and punitive damages, and prejudgment interest to which they are entitled;

H. That Relators be awarded all costs, attorneys' fees, and litigation expenses;

I. That the United States Government, the respective Plaintiff States, and Relators receive all relief, both at law and in equity, to which they may reasonably appear entitled.

Respectfully submitted,

/s/ Jennifer M. Verkamp
Jennifer M. Verkamp (0067198)
Frederick M. Morgan, Jr. (0027687)
Morgan Verkamp LLC
35 E. 7th St., Ste 600
Cincinnati, OH 45202
Tel : (513) 651-4400
Fax : (513) 651-4500
Email: jverkamp@morganverkamp.com

David J. Chizewer
William C. Meyers
Courtney R. Baron
Goldberg Kohn Ltd.
55 E. Monroe, Suite 3300
Chicago, IL 60603
Tel : (312) 201-4000
Fax : (312) 332-2196
Email: david.chizewer@goldbergkohn.com

Counsel for Relators

CERTIFICATE OF SERVICE

I certify that on this 29th day of August, 2014, a copy of the foregoing was served on all counsel of record through the United States District Court for the Southern District of Ohio's electronic filing system.

/s/ Jennifer M. Verkamp
Jennifer M. Verkamp, Esq.